Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

K103110

JAN 10 2011

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. SUBMITTER'S NAME	Abbott Vascular Inc.
2. SUBMITTER'S ADDRESS	26531 Ynez Road, Temecula, CA 92591
3. TELEPHONE	(951) 914-3243
4. FAX	(951) 914-0339
5. CONTACT PERSON	Suzanne Redman
6. DATE PREPARED	November 9, 2010
7. DEVICE TRADE NAME	TREK™ RX Coronary Dilatation Catheter MINI TREK™ RX Coronary Dilatation Catheter TREK™ OTW Coronary Dilatation Catheter MINI TREK™ OTW Coronary Dilatation Catheter
8. DEVICE COMMON NAME	• Coronary Dilatation Catheter • Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
9. DEVICE CLASSIFICATION NAME	PTCA Catheter (LOX)
10. PREDICATE DEVICE NAME	VOYAGER® RX Coronary Dilatation Catheter VOYAGER® NC Coronary Dilatation Catheter VOYAGER® OTW Coronary Dilatation Catheter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

11. DEVICE DESCRIPTION

11.1 TREK RX and MINI TREK RX Coronary Dilatation Catheter

The TREK RX and MINI TREK RX Coronary Dilatation Catheters are a rapid exchange co-axial design with a balloon at the distal tip. **Table 1** provides a matrix of the balloon diameters and lengths available.

Table 1 TREK RX and MINI TREK RX Balloon Sizes

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK RX							
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X
TREK RX							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50			X	X			
5.00			X	X			

The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. The coaxial shaft consists of a tubular inner and outer member. The inner member permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. The proximal shaft consists of a hypotube with a hub on the proximal end, a tapered distal section ending distal to the guide wire notch junction, along with brachial and femoral markers.

11.2 TREK OTW and MINI TREK OTW Coronary Dilatation Catheter

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are an over-the-wire co-axial design with a balloon at the distal tip. **Table 2** provides a matrix of the balloon diameters and lengths available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Table 2 TREK OTW and MINI TREK OTW Balloon Sizes

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK OTW							
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X
TREK OTW							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50			X	X			
5.00			X	X			

The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. The coaxial shaft consists of a tubular inner and outer member. The inner lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. Along the proximal portion of the shaft are brachial and femoral markers to aid in gauging the catheter's position relative to the guiding catheter tip when introducing the catheter through the guiding catheter. An adaption arm is located at the proximal end to provide access to the inflation lumen and guide wire lumen and allows connection with an inflation device.

12. INDICATIONS FOR USE

The TREK™ RX, MINI TREK™ RX, TREK™ OTW, and MINI TREK™ OTW are indicated for:

a) balloon dilatation of the stentotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;

b) balloon dilatation of a coronary artery occlusion of the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;

c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

13. TECHNOLOGICAL CHARACTERISTICS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

14. PERFORMANCE DATA

The TREK RX, MINI TREK RX, TREK OTW and MINI TREK OTW Coronary Dilatation Catheters were subjected to the following *in vitro* bench tests according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010:

- Catheter Preparation
- Catheter Profile (crossing and refolded)
- Balloon Inflation and Deflation
- Balloon Fatigue and Balloon Fatigue Within a Stent
- Balloon Rupture and Balloon Rupture Within a Stent
- Balloon Compliance
- Catheter Bond Tensile Strength
- Catheter Coating Particulate
- Kink and Flexibility
- Torque
- Radiopacity

Biocompatibility testing included cyctotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, and complement activation.

These in vitro bench and biocompatibility tests demonstrated that the TREK RX, MINI TREK RX, TREK OTW and MINI TREK OTW Coronary Dilatation Catheters met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and therefore, these devices may be considered substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular, Inc
c/o Ms. Suzanne Redman
Principal regulatory Affairs Associates
26531 Ynez Road
Temecula, CA 92591

JAN 10 2011

Re: K103110
Trade/Device Name: TREK™ RX Coronary Dilatation Catheter
MINI TREK™ RX Coronary Dilatation Catheter
TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: PTCA Catheters
Regulatory Class: Class II (two)
Product Code: LOX
Dated: December 29, 2010
Received: December 30, 2010

Dear Ms. Redman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

JAN 10 2011

INDICATIONS FOR USE

510(k) Number (if known): K103110

Device Names: TREK™ RX Coronary Dilatation Catheter
MINI TREK™ RX Coronary Dilatation Catheter
TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter

Indications for Use: The TREK™ RX, MINI TREK™ RX, TREK™ OTW, and MINI TREK™ OTW Coronary Dilatation Catheters are indicated for: a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perforusion;
b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segement elevation myocardial infarction;
c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

Prescription Use__X__ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103110

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular, Inc
c/o Ms. Suzanne Redman
Principal regulatory Affairs Associates
26531 Ynez Road
Temecula, CA 92591

JAN 10 2011

Re: K103110
Trade/Device Name: TREK™ RX Coronary Dilatation Catheter
MINI TREK™ RX Coronary Dilatation Catheter
TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: PTCA Catheters
Regulatory Class: Class II (two)
Product Code: LOX
Dated: December 29, 2010
Received: December 30, 2010

Dear Ms. Redman:

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If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

JAN 10 2011

INDICATIONS FOR USE

510(k) Number (if known): K103110

Device Names: TREK™ RX Coronary Dilatation Catheter
MINI TREK™ RX Coronary Dilatation Catheter
TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter

Indications for Use: The TREK™ RX, MINI TREK™ RX, TREK™ OTW, and MINI TREK™ OTW Coronary Dilatation Catheters are indicated for: a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perforusion;
b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segement elevation myocardial infarction;
c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

Prescription Use___X___ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103110

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 03, 2011

MS.

ABBOTT VASCULAR-CARDIAC THERAPIES
26531 YNEZ RD. MAILING P.O. BOX 9018
TEMECULA, CALIFORNIA 92589-9018
UNITED STATES
ATTN: SUZANNE REDMAN

510k Number: K103110

Product: MINI TREK(TM) RX AND TREK(TM)

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 08, 2010

MS.

ABBOTT VASCULAR-CARDIAC THERAPIES
26531 YNEZ RD. MAILING P.O. BOX 9018
TEMECULA, CALIFORNIA 92589-9018
UNITED STATES
ATTN: SUZANNE REDMAN

510k Number: K103110

Product: MINI TREK(TM) RX AND TREK(TM)

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Food and Drug Administration
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Silver Spring, MD 20993-0002

Abbott Vascular Inc.
c/o Suzanne Redman
Principal Regulatory Affairs Associate
26531 Ynez Road
Temecula, CA 92591

DEC - 2 2010

Re: K103110
Trade Name: MINI TREK RX, TREK RX, MINI TREK OTW, and TREK OTW Dilation Catheter
Dated: September 17, 2010
Received: October 8, 2010

Dear Ms. Redman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information.

1. Please address the following concerns regarding biocompatibility testing performed on your TREK/MINI TREK OTW devices:
    a. For Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Hemolysis (indirect method), and Material Mediated Pyrogenicity tests, please clarify the time between extract preparation and use, and storage conditions if stored.
    b. Please acknowledge that for all future submissions, your test reports will include the following information:
        - whether or not extracts were manipulated (filtered, centrifuged, etc.);
        - condition of extract; and
        - Time between extract preparation and use, and storage conditions if stored.

2. In your Soft Tip to Inner Member Tensile test for the OTW TREK catheters, it appears that the 2.25 x 30mm size experienced a significant decrease in tensile strength between baseline and 6 months. Please provide a statistical comparison of aged and baseline results, and provide a scientific or clinical justification for why you believe a significant decrease in tensile strength with aging does not raise a safety concern. Please acknowledge that for future submissions, you will provide statistical comparisons for performance tests with quantitative metrics to demonstrate whether a significant negative

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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effect on performance was observed post-aging. In addition, please acknowledge that you will not extend your shelf life if any of your devices do not meet the acceptance criteria set at baseline, for all of the tests performed.

3. For the colorant being used in the white foil proximal marker, please acknowledge your understanding that additional information is being requested of CFC International regarding their Type III DMF #17442 letter of authorization dated August 27, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

4. For the aqua colorant being used in the RX Catheter Clip, please acknowledge your understanding that additional information is being requested of Clariant regarding their Type III DMF #10640 letter of authorization dated September 10, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

5. For the colorant being used in the purple colorant used in the side arm, please acknowledge your understanding that additional information is being requested of CFC International regarding their MAF#0353 letter of authorization dated August 26, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

6. In your response to deficiency #10 of our August 9, 2010 letter (P810046/S235) regarding Crossing Profile, you indicate that your label claims compatibility with 5F guide catheters based on a 0.056" ID minimum for these guide catheters. However, your IFU currently only states "Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery" and are not limiting compatible accessories to 5F guide catheters. The labeling language regarding guide catheter selection is acceptable since you have identified the French size of the thickest part of each device size in your labeling (3.4Fr for all devices). However, it is unclear whether your testing sufficiently assesses the compatibility of the guide catheters expected to be used. Specifically, in response to deficiency #17f regarding Particulates testing (combined with simulated use testing), you have identified the accessory devices used in your testing but did not specify the accessory device sizes. Please provide this information.

7. Please address the following concerns regarding the lack of testing using the 5.0x15mm device size for Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing post-aging:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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a. You have performed an engineering study using baseline samples to identify the worst case device size for the TREK and Mini TREK catheters (RPT2073031), which examined Balloon Fatigue (without a stent) and Balloon Rupture. It is unclear from this test report whether the 2.75mm balloon is indeed the worst case when compared to the 5.0mm balloons, in part because the data from the shortest (6mm) and longest (30mm) were pooled. You have also provided Balloon Rupture testing using devices determined to be worst case from your initial engineering study (p. 6-72 of P810046/S235). From the test data provided in your P810046/S235 submission, the 5.0 x 15mm and 5.0 x 12mm size devices had the lowest Rupture Pressure and RBP at baseline, lower than that of the 2.75 x 30mm devices. Therefore, from the data presented, it is unclear whether the 2.75 x 30mm diameter devices used for post-aged testing is the worst case compared to one of the 5.0mm diameter devices. Please perform Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing on your worst case 5.0mm device size aged to your proposed shelf life, or provide additional data to support the 2.75 x 30mm size as the worst case.

b. You also noted in response to deficiency #13 regarding Balloon Rupture testing, that the data from the baseline 5.0 x 15mm devices give the appearance that this is the worst case size, but attribute this to lot-to-lot manufacturing variations. Since it appears that you have not performed Balloon Rupture testing on different lots for a given device size, we cannot conclude that differences observed between different sizes are due to different lots and not due to the device size. Please keep this in mind, should you choose to provide additional justification for testing the 2.75x30mm devices post-aging.

8. Please address the following concerns regarding your Balloon Rupture test:

a. Per our Guidance *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* the compliance chart may include pressures up to (but not exceeding) 25% above the RBP, if you provide data and statistics demonstrating that 99% of the balloons will not fail at the listed pressure with 95% confidence. It is unclear from the testing provided whether 99% of your catheters will not fail at 17 atm with 95% confidence, post aging, per the compliance chart in your IFU. Please clarify.

b. If you determine that your data do not support the 17 atm failure pressure, please revise your compliance chart accordingly.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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9. Please address the following concerns regarding your Particulates Testing:

   a. You state that for baseline testing, the 2.0 x 6mm and the 5.0 x 15mm devices were tested as representative of the smallest and largest sizes (diameter and length) in the balloon matrix that are indicated for the post-stent dilatation indication, and the 4.0 x 30mm devices were tested as a worst case because it has the largest balloon surface area that contacts the stents. You also justify testing only the 4.0 x 30mm devices post aging because this size had the highest particulation at baseline. Since you did not test the 2.0 x 30mm size, which is one of the 4 corners of your device size matrix, at baseline, we cannot determine conclusively that the 4.0 x 30mm is the worst case size. In particular, the 2.0 x 6mm devices had greater than $1/5^{th}$ the mean particulates count of the 4.0 x 30mm devices. This suggests that the 4.0 x 30mm devices may have appeared to be worst case due to the longer length of the balloon, but in fact, the 2.0 x 30mm devices may be the true worst case devices in terms of particulates generation. Please repeat testing using the 2.0 x 30mm devices at baseline and provide an updated test report.

   b. If you determine from the 2.0 x 30mm devices tested at baseline that this size is the true worst case in terms of particulates generation, please also perform particulates testing using 2.0 x 30mm devices aged to your proposed shelf life. Please make sure to incorporate recommendations made in deficiency #17, such as including a $\geq$50µm particle bin size, accounting for particles from flushing the accessory devices after placement, etc. In addition, if the 2.0 x 30mm devices are determined to be the worst case, please also perform a visual assessment of the coating.

   c. Please make sure to include both RX and OTW devices for this additional testing, or provide a scientific justification for only using one device configuration.

   d. In your particulates validation testing, it appears you have used a slightly different 2.0mm device size test fixture than what was actually used to assess particulates generation (per your November 24, 2010 email). Specifically, the tubing diameter used within the tortuosity base plate was slightly different. While this is acceptable since validation results for the 4.0mm device fixture with similar tortuosity to the 2.0mm fixture and a further larger tubing size showed similar results, please acknowledge that for future testing you will use the same exact test setup and methods in your validation testing as in your actual device testing. Please also acknowledge that if you have differences in your validation test setup or protocol (flushing etc.) that you will clearly identify and justify these differences in future submissions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf**

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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If you have any questions concerning the contents of the letter, please contact Erica Takai at (301) 796-6535 or erica.takai@fda.hhs.gov, or Ashley Boam at ashley.boam@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ashley B. Boam, MSBE, Chief
Interventional Cardiology Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 22, 2010

ABBOTT VASCULAR-CARDIAC THERAPIES
26531 YNEZ RD. MAILING P.O. BOX 9018
TEMECULA, CALIFORNIA 92589-9018
UNITED STATES
ATTN: SUZANNE REDMAN

510k Number: K103110
Received: 10/8/2010
Product: MINI TREK(TM) RX AND TREK(TM)

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process.. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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betamethasone acetate equivalent to 0.89 mg betamethasone alcohol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill one or two drops of solution in the conjunctival sac three or four times a day.

(2) *Indications for use.* For treatment of external bacterial infections of the eye (conjunctiva and cornea).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 1, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–22276 Filed 9–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2000–P–0924] (formerly Docket No. FDA–2000–P–1533)

Cardiovascular Devices; Reclassification of Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the device type, standard percutaneous transluminal coronary angioplasty (PTCA) catheters, from class III (premarket approval) into class II (special controls). Cutting/scoring PTCA catheters remain in class III and continue to require premarket approval applications (PMAs). FDA is reclassifying these devices in accordance with the Federal Food, Drug, and Cosmetic Act (the act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" that will serve as the special control for the reclassified device type.

DATES: This final rule is effective October 8, 2010.

FOR FURTHER INFORMATION CONTACT: Kathryn O'Callaghan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6349.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f)) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)); or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification (510(k)) procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a PMA until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(3) of the act (21 U.S.C.360c(f)(3)). This section states that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or that a manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

The PTCA catheter is a postamendments device classified into class III under section 513(f)(1) of the act. Therefore, the device cannot be placed in commercial distribution unless it is subject to an approved premarket approval application (PMA) under section 515 of the act (21 U.S.C. 360e) or is reclassified.

On September 21, 2000, FDA filed a petition submitted under section 513(f)(3) of the act from COOK requesting reclassification of PTCA catheters from class III into class II. This reclassification petition did not include cutting or scoring PTCA catheters. In order to reclassify the PTCA catheter into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and

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effectiveness of the device for its intended use.

The COOK petition requested reclassification of PTCA catheters from class III to class II when indicated for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested changes in classification. FDA also asked the Circulatory System Devices Panel for its recommendation on the reclassification of PTCA catheters when used for treatment of acute myocardial infarction (MI), treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

III. Device Description

FDA identifies this generic type of device, the subject of this reclassification, as follows: *Standard Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.* A PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

FDA is also issuing the following identification for the devices that will remain in class III: A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

IV. Recommendation of the Panel

At a public meeting on December 4, 2000, the Panel recommended (seven to one) that PTCA catheters be reclassified from class III to class II, when indicated for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion; or for treatment of acute myocardial infarction. The Panel did not recommend reclassification for PTCA catheters indicated for the treatment of in-stent restenosis and/or post-deployment stent expansion. The Panel recommended a guidance document, labeling, and postmarket surveillance as special controls. The Panel stated that the special controls will diminish some of the risks to health associated with certain PTCA catheters. The guidance document and labeling controls are intended to ensure the appropriate performance and use of the device by physicians. The Panel recommended postmarket surveillance as a special control to confirm that the other special controls being applied to these devices would be sufficient to ensure that there would not be an increase in adverse consequences to patients. In summary, the Panel believed that class II with special controls would provide reasonable assurance of the safety and effectiveness of the device.

The Panel recommended that PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent expansion not be included because of a lack of sufficient information about this use. Since the Panel meeting, however, additional data regarding this use have become available and have been reviewed by the agency.

FDA considered the Panel's recommendations and tentatively agreed that PTCA catheters, other than cutting/scoring PTCA catheters, should be reclassified from class III into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

Although the Panel included the possibility of requiring postmarket surveillance in their recommendation, FDA did not agree that specific postmarket surveillance such as device tracking or postapproval studies are needed for PTCA catheters. FDA believes that periodic assessment of adverse event reports through medical device reporting submitted to the agency is sufficient to address adverse effects caused by these devices and is the least burdensome way to gather this data for PTCA catheters. This practice is consistent with the manner in which these devices have been regulated as class III devices since the Panel meeting.

Further, after a review of adverse event reports submitted to FDA's Manufacturer and User Facility Device Experience (MAUDE) Database, the agency believes that the types of risks associated with the use of PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent expansion are similar enough to the risks associated with treatment of de novo lesions, such that the special controls discussed at the Panel meeting, with the addition of recommendations for specific nonclinical performance testing and the recommendation that in-stent restenosis patients be included in the clinical evaluation, when necessary, are adequate to control the risks to health for these devices.

Accordingly, in the **Federal Register** of May 30, 2008 (73 FR 31123), FDA issued the Panel's recommendation for public comment. FDA did not receive any comments regarding the Panel's recommendation. Elsewhere in this issue of the **Federal Register**, comments received regarding the draft guidance document are addressed in the notice of availability announcing the special controls guidance document.

V. FDA's Conclusion

After reviewing the data in the petition and presented at the Panel meeting, and after considering the Panel's recommendation and the comments on the notice of panel recommendation, FDA has determined that the device type, standard percutaneous transluminal coronary angioplasty (PTCA) catheters, can be reclassified from class III into class II.

On August 19, 2010, FDA issued an order to the petitioner reclassifying the devices into class II (special controls). The order also identified the special control applicable to these devices as a guidance document entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters." This class II special controls guidance document is now the special control for this device type.

An alternative approach to the special controls guidance document may be used if such approach satisfies the applicable statute and regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for this device type will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Accordingly, as required by 21 CFR 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the standard percutaneous transluminal coronary angioplasty (PTCA) catheters, from class III into class II. In addition, FDA is issuing this final rule to codify the reclassification of the device by adding new § 870.5100.

VI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device type, from class III to class II, will relieve manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification will reduce regulatory costs with respect to this device, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Based on an assessment of identified risks associated with the use of PTCA catheters, FDA finds the requirements associated with a premarket approval as a class III device do not provide an added public health benefit over those that would result from the requirements under a class II (with special controls). At the same time, PTCA catheter manufactures, as makers of class III devices, bear all the costs associated with a premarket approval, including the cost of submitting the premarket approval application (PMA) and payment of user fees. One previously published estimate (in 73 FR 7497) suggests that the costs to prepare a PMA could potentially reach $1,000,000, in addition to user fees of $217,787 in FY (fiscal year) 2010.

In contrast, if reclassification becomes final, manufacturers of a PTCA catheter would pay a user fee of $4,007 for a 510(k) submission in FY 2010. While we do not have data to estimate the cost of preparing a 510(k) submission, several different factors indicate that it would be less than the cost of a PMA. For example, a firm does not have to submit manufacturing information in its 510(k), which is required for a PMA application, thereby reducing the burden and documentation needed. Given the ability to evaluate nonclinical testing in a direct comparison to a predicate device in a 510(k), FDA anticipates that most new PTCA catheters will not require clinical data to support 510(k) clearance, whereas all PMAs have to include some form of clinical data to support PMA approval. This difference will result in a significant reduction in cost for the device manufacturer. A PMA also requires the sponsor to prepare a draft summary of safety and effectiveness document, which is not required for a 510(k).

Based on the most recent 5 years, FDA estimates the following annual number of submissions received for PTCA catheters: 15 "30-day Notice" PMA supplements, 1 "Normal 180-day Track" PMA supplement, and 2 "Real-Time Process" PMA supplements. (Note: FDA has not received any "Panel-Track" supplements or original PMA submissions for this device in the past 5 years.) A "30-day Notice" is submitted for changes to a manufacturing process or method and assessed a user fee of $3,485 in FY 2010. When reclassification is final, these types of changes will not require clearance prior to the firm making the change in the majority of cases. Modifications to the method of manufacture of a device could require submission of a 510(k) if the changes could significantly affect the safety or effectiveness of the device, such as those that would currently require a "Real-Time Process" or "Panel-Track" PMA supplement. Based on FDA's experience, submission of a 510(k) for a modification to the method of manufacturing would be rare.

In summary, this device reclassification would reduce the existing burden on manufacturers of PTCA catheters. The application of class II (with special controls) requirements would be consistent with the principle of applying the least degree of regulatory control necessary to provide reasonable assurance of safety and effectiveness.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe *** a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain state requirements "different from or in addition to" certain Federal requirements applicable to devices. (See section 512 of the act (21 U.S.C. 360k); *Medtronic* v. *Lohr*, 518 U.S. 470 (1996); *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008)). The special controls established by this final rule create "requirements" for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

IX. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This guidance, "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters," references previously approved collections of information found in FDA regulations.

List of Subjects in 21 CFR Part 870

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 870.5100 is added to subpart F to read as follows:

§ 870.5100 Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.

(a) *Standard PTCA Catheter*—(1) *Identification.* A PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

(2) *Classification.* Class II (special controls). The special control for this device is "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters." See § 870.1(e) for the availability of this guidance document.

(b) *Cutting/scoring PTCA Catheter*—(1) *Identification.* A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

(2) *Classification.* Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 870.3.

Dated: August 31, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–22304 Filed 9–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AN54

Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease); Correction

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; correction.

SUMMARY: The Department of Veterans Affairs (VA) published in the **Federal Register** on August 31, 2010, a document amending the adjudication regulations concerning the presumptive service connection for certain diseases based upon the most recent National Academy of Sciences Institute of Medicine committee report, Veterans and Agent Orange: Update 2008. In the preamble of that document, VA inadvertently included an incorrect Web site address. This document corrects the Web site address.

DATES: *Effective Date:* This correction is effective September 8, 2010.

FOR FURTHER INFORMATION CONTACT: Janet Coleman, Office of Regulation Policy and Management, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–4902 (This is not a toll-free number.).

SUPPLEMENTARY INFORMATION: On August 31, 2010, VA published in the **Federal Register** (75 FR 53202), an amendment to 38 CFR 3.309 to add hairy cell leukemia and other chronic B-cell leukemias, Parkinson's disease and ischemic heart disease to the list of diseases subject to presumptive service connection based on herbicide exposure. On page 53215 of that document, in the third column, second paragraph, we inadvertently provided a Web site of: "*http://vaww1.va.gov/ORPM/FY_2010_Published_VA_Regulations.asp*", which is corrected to read: "*http://www1.va.gov/ORPM/FY_2010_Published_VA_Regulations.asp*".

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Approved: September 2, 2010.

Robert C. McFetridge,

Director, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2010–22281 Filed 9–7–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AH95

Medical; Nonsubstantive Miscellaneous Changes; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Correcting amendment.

SUMMARY: The Department of Veterans Affairs (VA) published a final rule in the **Federal Register** on May 13, 1996 (61 FR 21964), amending its medical regulations in 38 CFR part 17 by making a number of nonsubstantive changes. Specifically, section numbers were redesignated, redundant and obsolete material was removed, certain position and organizational titles were changed, and material previously deleted was restored. The document contained an error in an amendatory instruction. We removed portions of § 17.31 and inadvertently redesignated § 17.31(b)(5) as the new § 17.31, creating two sections for § 17.31. This document will correct that error by removing the second, obsolete § 17.31.

DATES: *Effective Date:* September 8, 2010.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(5) Inter-agency

(b)(5) Inter-agency

(b)(5) Inter-agency

(b)(5) Inter-agency

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 20, 2010

ABBOTT VASCULAR INC.
REGULATORY AFFAIRS
26531 YNEZ ROAD
TEMECULA, CALIFORNIA 92591
UNITED STATES
ATTN: SUZANNE REDMAN

Dear SUZANNE REDMAN:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your PMA AMENDMENT. This PMA AMENDMENT has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

PMA Number: P810046/S235/A002
Dated: 17-Sep-2010
Date Received: 20-Sep-2010
Device: TREK RX CORONARY DILATATION CATHETER AND MINI TR

Any questions concerning this submission should be directed to the undersigned at (301)796-5610. All future correspondence regarding this PMA should be identified with the PMA number assigned above and should be submitted with the required number of copies to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

In future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopies Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm. To ensure the electronic copy is complete, it is essential that you: (1) state in your

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

cover letter that you are providing an electronic copy as per FDAs instructions and that it is an exact duplicate of the paper copy and (2) follow the required structure of the files and/or folder described in the instructions with respect to the naming convention, descriptive names for files and folders, use of folders for volumes only, and placement at the root of the CD/DVD.

Records processed under FOIA Request #2014-8140 Released by CDRH on 02-01-2016

Sincerely yours,

Senora F. Smallwood
Consumer Affairs Specialist
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110 Released by CDRH on 02-01-2016

Abbott Vascular Inc.
Regulatory Affairs
26531 Ynez Road
Temecula, CA 92591

P810046/S235/A2/C2
V1

September 17, 2010

Document Mail Center (W066-G609)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
SEP 20 2010
Received

SUBJECT: Amendment to PMA Supplement P810046/S235 for the TREK™ RX Coronary Dilatation Catheter and MINI TREK™ RX Coronary Dilatation Catheter

To Whom It May Concern:

Please find enclosed an amendment to PMA Supplement P810046/S235 for the TREK™ RX Coronary Dilatation Catheter and MINI TREK™ RX Coronary Dilatation Catheter.

The purpose of this amendment is twofold: a) to respond to the deficiencies received in the letter from FDA dated August 9, 2010, and b) to amend the supplement with additional information and data to support an over-the-wire (OTW) delivery platform, TREK™ OTW and MINI TREK™ OTW Coronary Dilatation Catheters, in addition to the rapid exchange (RX) previously included in this supplement.

On September 2, 2010, Abbott Vascular and FDA held a teleconference to discuss Abbott Vascular's proposed responses to this deficiency and further clarify FDA's requests. The minutes of this teleconference are included in **Appendix A7-1**. During the teleconference FDA requested that Abbott Vascular provide colorant information for the indirect patient contact components of the device in the final submitted responses as well as the direct patient contact colorant information. For each of Abbott Vascular's responses, colorant information is also being included for the TREK OTW and MINI TREK OTW catheters which are included in **Attachment 20**. Based on the totality of all of the information presented in the response to the colorant question, Abbott Vascular believes there are no anticipated adverse effects that would result from any of the colorants used in the TREK RX, MINI TREK RX, TREK OTW and MINI TREK OTW Coronary Dilation Catheters.

Abbott
A Promise for Life

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Responses to each deficiency are included as individual attachments with supporting appendices where applicable. This includes Abbott Vascular's response to the colorant related deficiency based upon the September 2, 2010 teleconference with FDA. Minutes of this meeting are included in **Appendix A7-1**.

In response to Deficiency 18 regarding FDA's request to change the room temperature value from 20°C to 25°C to calculate the accelerated aging factor, AV has made the required changes to the protocol to reflect this and the updated protocol is provided in **Appendix 18-1**. Abbott Vascular will extend the shelf life up to three years as sufficient accelerated aging data is collected based on the amended test protocol and acceptance criteria as submitted to the agency in this amendment. Shelf life updates will be reported to the agency via the periodic report along with summaries of real time aging data as completed.

This amendment also includes information and data in support of the TREK™ OTW and MINI TREK™ OTW Coronary Dilatation Catheters. The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are similar in design, materials, and indications to the TREK RX and MINI TREK RX Coronary Dilatation Catheter (P810046/S235, submitted March 19, 2010.). The distal portion of the catheters from the mid-lap joint to the tip, including all balloon diameters and lengths, is identical to the distal portion of the TREK RX and MINI TREK RX. The proximal portions of the TREK OTW and MINI TREK OTW differ from the RX platform to allow for an over-the-wire design.

To demonstrate the safety and efficacy of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters, *in vitro* bench testing was conducted in accordance with the *Draft Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* May 30, 2008. Accelerated aging was conducted to substantiate a shelf life of one (1) year. Where device design and manufacturing is identical to the TREK RX and MINI TREK RX, i.e., the distal portions, testing previously performed and included in P810046/S235 is leveraged and additional testing of the OTW version of the device was not repeated. The table below provides information in regards to testing conducted on the TREK OTW and MINI TREK OTW along with testing which is leveraged from the TREK RX and MINI TREK RX. Where testing was repeated due to differences in device design between the RX and OTW platforms, the results are included with this response as indicated in the table below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Test Completed	Data Leveraged From RX	Location in Attachment 20 (page)
(b)(4)		

Two paper copies of this amendment to PMA Supplement P810046/S235 have been submitted to the Document Mail Center. An electronic copy, per FDA instructions, has been provided in lieu of a third paper copy. The electronic copy is an exact duplicate of the paper copy. The data and other information contained in this PMA supplement are confidential, and the protection afforded to such confidential information by 18 USC 1950, 21 USC 331 (I), 5 USC 552, and other applicable laws is hereby claimed. The information contained within the attached PMA Supplement is presented in accordance with 21 CFR § 814.20 and § 814.39.

If you have any questions or require any additional information, please contact me at (951) 914-3243 or Sean Mullin, Regulatory Affairs Manager, at (941) 491-3101. I may

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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also be reached by fax at (951) 914-0339 or by e-mail at suzanne.redman@av.abbott.com.

Sincerely,

Suzanne Redman
Principal Regulatory Affairs Associate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
September 17, 2010		

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☒ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Abbott Vascular	2024168		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	951-914-3243		
Street Address	**FAX Number** *(including area code)*		
26531 Ynez Road	951-914-0339		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Temecula	CA	92591	USA
Contact Name			
Suzanne Redman			
Contact Title	**Contact E-mail Address**		
Principal Regulatory Affairs Associate	suzanne.redman@av.abbott.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, *if different from above*)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
Street Address	**FAX Number** *(including area code)*		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- [x] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [x] Response to FDA correspondence:

deficiencies and amend with OTW info

- [ ] Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1			
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Coronary Dilatation Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	MINI TREK(tm) RX and TREK(tm) RX Coronary Dilatation Catheter	1	See Attachment 1
2	MINI TREK(tm) OTW and TREK(tm) OTW Coronary Dilatation Catheter	2	See Attachment 1
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 P810046	2 P810046/S226	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LOX		☐ Class I ☐ Class II
Classification Panel		☒ Class III ☐ Unclassified
Cardiovascular Devices Panel		

Indications *(from labeling)*

The MINI TREK and TREK RX & OTW Coronary Dilatation Catheters are indicated for: a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion; b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction; c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H **MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 411

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ASTM F1886	American Society for Testing and Materials	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection		01/01/1998
2	ASTM F88	American Society for Testing and Materials	Standard Test Method for Seal Strength of Flexible Barrier Materials		01/01/2007
3	ASTM F720	American Society for Testing and Materials	Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test		01/01/2007
4	ASTM F756	American Society for Testing and Materials	Standard Practice for Assessment of Hemolytic Properties of Materials		12/1/2008
5	USP <85>	United States Pharmacopeia	*Bacterial Endotoxins Test*	USP 31	01/01/2009
6	USP <161>	United States Pharmacopeia	Transfusion and Infusion Assemblies and Similar Medical Devices	USP 31	01/01/2009
7			See Attachment 3 for additional Standards cited		

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

ATTACHMENT 1

Section F: Model Names and Model Numbers

TREK™ RX Coronary Dilatation Catheter					
Model Number	**Diameter (mm)**	**Length (mm)**	**Model Number**	**Diameter (mm)**	**Length (mm)**
1012271-06	2.25	6	1012275-12	3.25	12
1012271-08	2.25	8	1012275-15	3.25	15
1012271-12	2.25	12	1012275-20	3.25	20
1012271-15	2.25	15	1012275-25	3.25	25
1012271-20	2.25	20	1012275-30	3.25	30
1012271-25	2.25	25	1012276-06	3.50	6
1012271-30	2.25	30	1012276-08	3.50	8
1012272-06	2.50	6	1012276-12	3.50	12
1012272-08	2.50	8	1012276-15	3.50	15
1012272-12	2.50	12	1012276-20	3.50	20
1012272-15	2.50	15	1012276-25	3.50	25
1012272-20	2.50	20	1012276-30	3.50	30
1012272-25	2.50	25	1012277-06	3.75	6
1012272-30	2.50	30	1012277-08	3.75	8
1012273-06	2.75	6	1012277-12	3.75	12
1012273-08	2.75	8	1012277-15	3.75	15
1012273-12	2.75	12	1012277-20	3.75	20
1012273-15	2.75	15	1012277-25	3.75	25
1012273-20	2.75	20	1012277-30	3.75	30
1012273-25	2.75	25	1012278-06	4.00	6
1012273-30	2.75	30	1012278-08	4.00	8
1012274-06	3.00	6	1012278-12	4.00	12
1012274-08	3.00	8	1012278-15	4.00	15
1012274-12	3.00	12	1012278-20	4.00	20
1012274-15	3.00	15	1012278-25	4.00	25
1012274-20	3.00	20	1012278-30	4.00	30
1012274-25	3.00	25	1012279-12	4.50	12
1012274-30	3.00	30	1012279-15	4.50	15
1012275-06	3.25	6	1012280-12	5.00	12
1012275-08	3.25	8	1012280-15	5.00	15

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Section F: Model Names and Model Numbers - *Continued*

MINI TREK™ RX Coronary Dilatation Catheter					
Model Number	**Diameter (mm)**	**Length (mm)**	**Model Number**	**Diameter (mm)**	**Length (mm)**
1012269-06	1.50	6	1012270-08	2.00	8
1012269-08	1.50	8	1012270-12	2.00	12
1012269-12	1.50	12	1012270-15	2.00	15
1012269-15	1.50	15	1012270-20	2.00	20
1012269-20	1.50	20	1012270-25	2.00	25
1012270-06	2.00	6	1012270-30	2.00	30

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Section F: Model Names and Model Numbers - *Continued*

TREK™ OTW Coronary Dilatation Catheter					
Model Number	**Diameter (mm)**	**Length (mm)**	**Model Number**	**Diameter (mm)**	**Length (mm)**
1012404-06	2.25	6	1012408-12	3.25	12
1012404-08	2.25	8	1012408-15	3.25	15
1012404-12	2.25	12	1012408-20	3.25	20
1012404-15	2.25	15	1012408-25	3.25	25
1012404-20	2.25	20	1012408-30	3.25	30
1012404-25	2.25	25	1012409-06	3.50	6
1012404-30	2.25	30	1012409-08	3.50	8
1012405-06	2.50	6	1012409-12	3.50	12
1012405-08	2.50	8	1012409-15	3.50	15
1012405-12	2.50	12	1012409-20	3.50	20
1012405-15	2.50	15	1012409-25	3.50	25
1012405-20	2.50	20	1012409-30	3.50	30
1012405-25	2.50	25	1012410-06	3.75	6
1012405-30	2.50	30	1012410-08	3.75	8
1012406-06	2.75	6	1012410-12	3.75	12
1012406-08	2.75	8	1012410-15	3.75	15
1012406-12	2.75	12	1012410-20	3.75	20
1012406-15	2.75	15	1012410-25	3.75	25
1012406-20	2.75	20	1012410-30	3.75	30
1012406-25	2.75	25	1012411-06	4.00	6
1012406-30	2.75	30	1012411-08	4.00	8
1012407-06	3.00	6	1012411-12	4.00	12
1012407-08	3.00	8	1012411-15	4.00	15
1012407-12	3.00	12	1012411-20	4.00	20
1012407-15	3.00	15	1012411-25	4.00	25
1012407-20	3.00	20	1012411-30	4.00	30
1012407-25	3.00	25	1012412-12	4.50	12
1012407-30	3.00	30	1012412-15	4.50	15
1012408-06	3.25	6	1012413-12	5.00	12
1012408-08	3.25	8	1012413-15	5.00	15

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Section F: Model Names and Model Numbers - *Continued*

MINI TREK™ OTW Coronary Dilatation Catheter					
Model Number	**Diameter (mm)**	**Length (mm)**	**Model Number**	**Diameter (mm)**	**Length (mm)**
1012402-06	1.50	6	1012403-08	2.00	8
1012402-08	1.50	8	1012403-12	2.00	12
1012402-12	1.50	12	1012403-15	2.00	15
1012402-15	1.50	15	1012403-20	2.00	20
1012402-20	1.50	20	1012403-25	2.00	25
1012403-06	2.00	6	1012403-30	2.00	30

ATTACHMENT 2

Section F: FDA document numbers of all prior related submissions

1 P810046	2 P810046/S201	3 P810046/S216	4 P810046/S217	5 P810046/S218	6 P810046/S219
7 P810046/S220	8 P810046/S222	9 P810046/S223	10 P810046/S225	11 P810046/S226	12 P810046/S227
13 P810046/S228	14 P810046/S230	15 P810046/S231	16 P810046/S232	17 P810046/S218	18 P020047
19 P020047/S017	20 P970020/S042	21 P070015	22 K972484	23 P880003/S090	

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ATTACHMENT 3

Section I: Utilization of Standards - *Continued*

Standards No.	Standards Organization	Standards Title	Date
USP 31 <151>	United States Pharmacopeia	Pyrogen Test	2009
ISO 11607-1	International Organization for Standardization	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	2006
ISO 11607-2	International Organization for Standardization	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	2006
ISO 10993-1	International Organization for Standardization	Biological evaluation of medical devices – Part 1: Evaluation and testing	2003
ANSI/AAMI/ISO 10993-5	American National Standards Institute / American Association of Medical Instrumentation / International Organization for Standardization	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity	1999
ISO 10993-7	International Organization for Standardization	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals	2008
ISO 10993-10	International Organization for Standardization	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity	2002
ANSI/AAMI/ISO 10993-11	American National Standards Institute / American Association of Medical Instrumentation / International Organization for Standardization	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	2006
ISO 10993-12	International Organization for Standardization	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	2007
ISO 14644-1	International Organization for Standardization	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	1999
ISO 14698-1	International Organization for Standardization	Cleanrooms and associated controlled environments – Biocontamination control – Part 1: General principles and methods	2003

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Standards No.	Standards Organization	Standards Title	Date
ISO 14698-2	International Organization for Standardization	Cleanrooms and associated controlled environments – Biocontamination control – Part 2: Evaluation and interpretation of biocontamination data	2003
ISO 11135	International Organization for Standardization	Medical devices – Validation and routine control of ethylene oxide sterilization	1994

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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	6.3 Packaging	2	A20.6-6
	6.4 *In Vitro* Bench Testing	2	A20.6-7
	6.5 Risk Analysis	2	A20.6-139
7.0	Sole Investigator	2	A20.7-1
8.0	Bibliography	2	A20.8-1
9.0	Device Samples	2	9-1
10.0	Labeling	2	10-1
11.0	Environmental Assessment	2	11-1
Appendix A20-I – Biocompatibility Reports		2	
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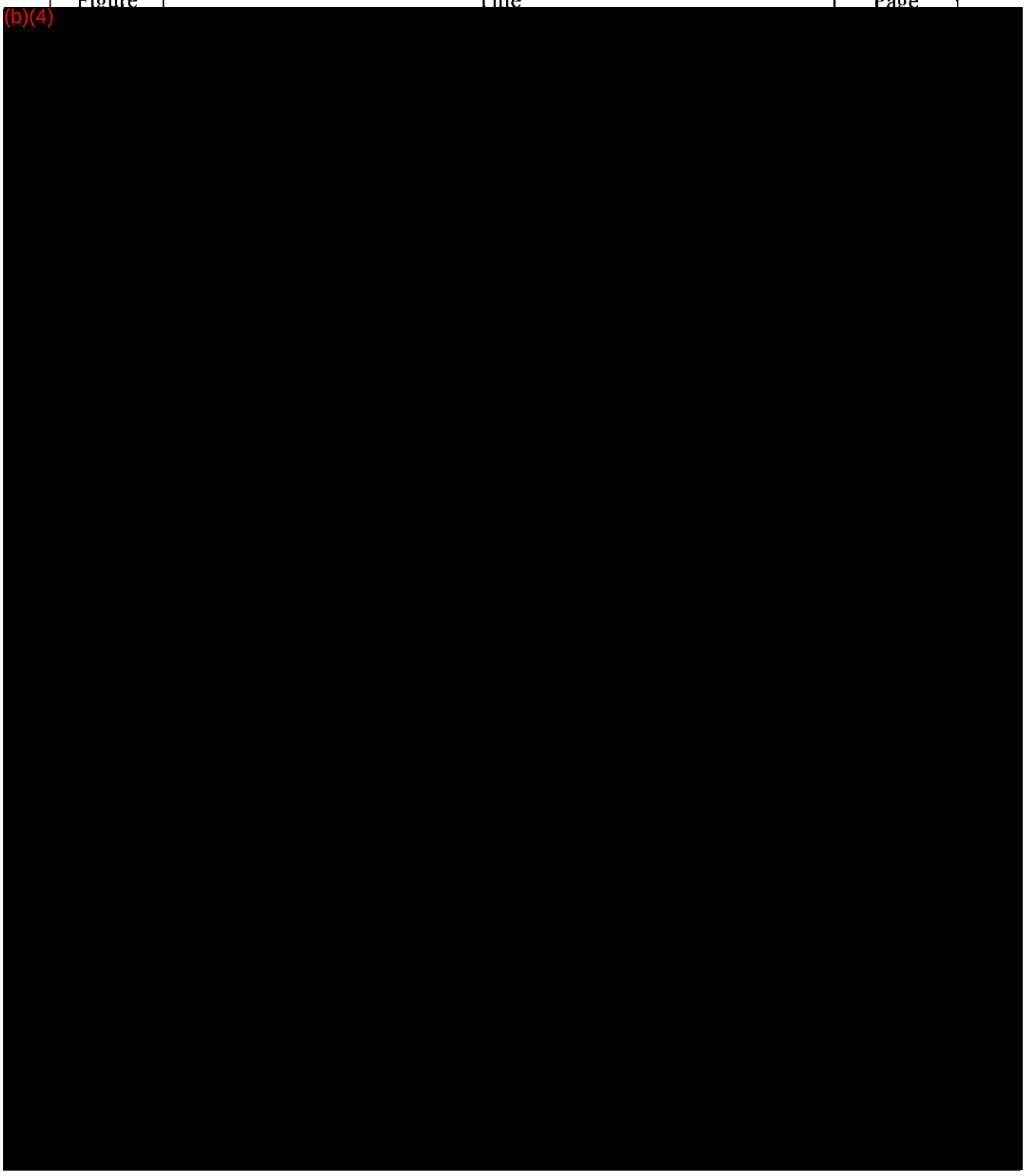
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ATTACHMENT 1

Question 1:

You have performed biocompatibility testing on MINI TREK devices but not on the Trek devices. To justify this, you stated that the Pebax 70D / Pebax 63D co-extruded balloons used in the Trek devices are identical in materials and subjected to the identical type of manufacturing processes as the balloons for the Voyager NC Coronary Dilatation Catheter. However, the soft tip, and inner and outer member materials to which the balloon is fused onto are different from the TREK and Voyager devices and it is unclear whether this manufacturing step with different combination of materials may alter the biocompatibility of the final device. Please perform additional biocompatibility testing on final sterilized TREK devices or provide additional justification on why you believe the combination of different balloon, soft tip, and inner and outer member materials would not affect biocompatibility. This may be achieved through comparison of extracts (polar, non-polar, and MEM used for cytotoxicity testing) of the distal catheter segment, which includes part of the distal shaft and balloon, for the TREK and MINI TREK to demonstrate that the chemical leachants are the same.

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[redacted]

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Table A1-1 TREK RX and MINI TREK RX Materials Comparison

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With respect to the laser processing of the soft tip, and inner and outer member materials to which the balloon is fused, Pebax is the trade name for polyether block amide copolymer manufactured by Arkema, with 70D or 63D referring to Shore D durometer. Pebax 63D and Pebax 70D are comprised of polyamide block and polyether block. Pebax 63D has a higher polyether block content which makes it a lower durometer. The laser bonding process used to bond the balloon to the catheter heats the Pebax balloon to temperatures above the melting point. Melting temperatures of Pebax 70D and 63D are 172°C and 169°C, respectively. During the melting, a blend of the polyether and the polyamide is created. In the case of the 63D/72D joint vs. the 70D/72D joint, there is a slightly higher amount of polyether and a slightly lower amount of polyamide. Due to the mixing effect that occurs during the melting, the constituents in the catheter remain unchanged regardless of the durometer. Therefore, the distal and proximal laser processes of two balloons with different durometers of the same materials are considered identical and do not present additional questions related to biocompatibility.

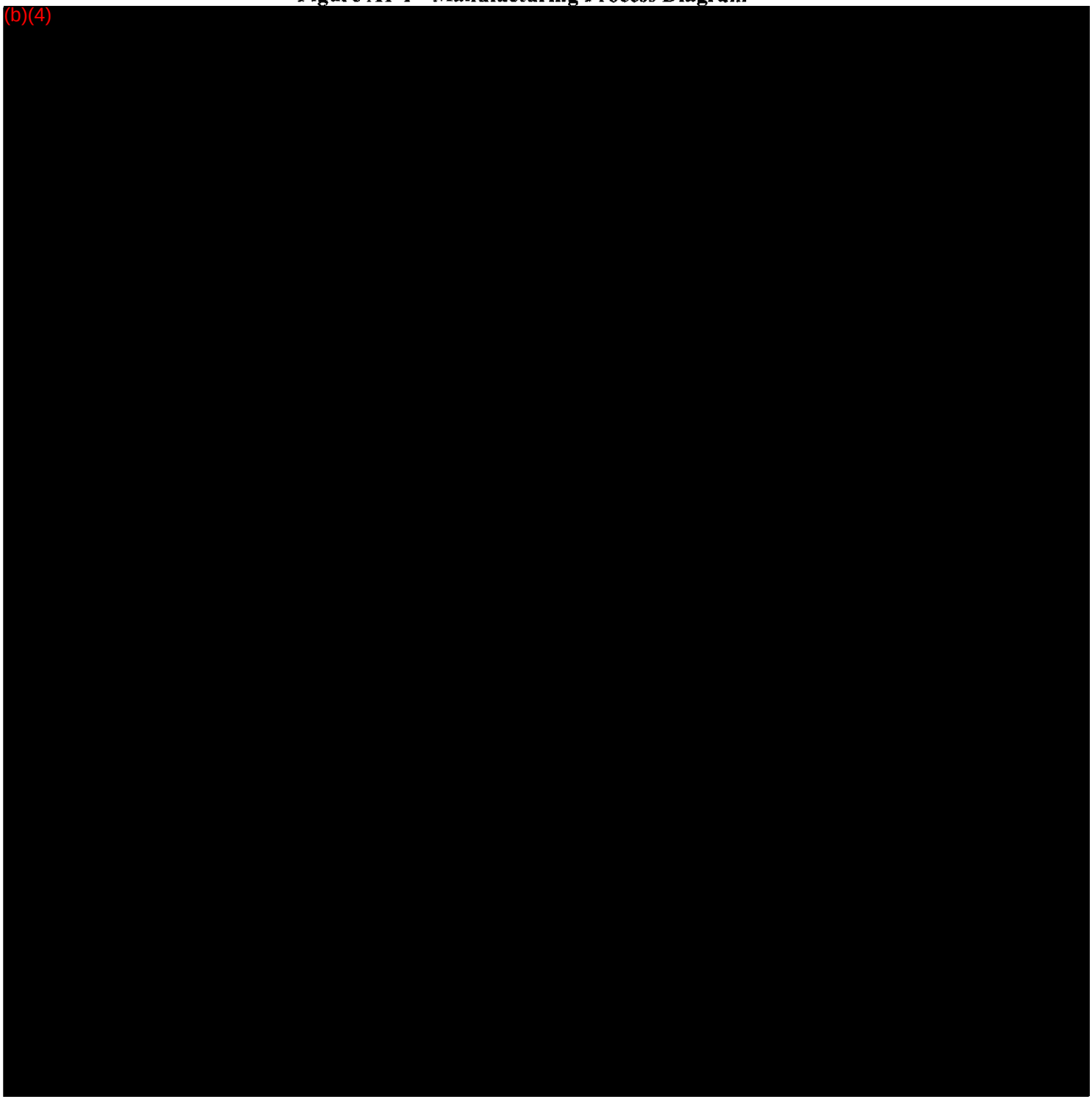
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Figure A1-1 below outlines the manufacturing processes used to manufacture the MINI TREK RX and the TREK RX. Highlighted in yellow in the figure are the laser processes where the balloon materials differ from MINI TREK RX to TREK RX.

Figure A1-1 Manufacturing Process Diagram

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The biocompatibility test reports included in Appendix I of P810046/S235 contain the biocompatibility testing specific to TREK RX and MINI TREK RX. This testing was conducted in accordance with ISO 10993-1:2003, *Biological evaluation of medical devices – Part 1: Evaluation and testing*, and *Draft Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*.

While the distal portion, from the tip to the midlap joint, of the TREX RX, MINI TREK RX, TREK OTW and MINI TREK OTW are identical to one another, the proximal portion of the OTW platforms differs somewhat from the RX platforms. Therefore, in accordance with ISO 10993-1:2003 and FDA's draft guidance for PTCA catheters, biocompatibility testing was repeated for the TREK OTW and MINI TREK OTW and the results of this testing, using the TREK OTW, are included in **Attachment 20, Section 6.1**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ATTACHMENT 2

Question 2:

In your biocompatibility test reports from Pacific BioLabs, the test article was identified as "Xcalibur RX" and as a "delivery system, needle, and a clamp." In your July 29, 2010 email, you clarified that a needle is not part of the Trek or Mini Trek device. Furthermore, the clamp, which appears to refer to the dilatation catheter clip, is not a patient contacting portion of the device, as it is used to keep the catheter coiled when not in use. Therefore, extracts used in the tests performed by Pacific BioLabs (cytotoxicity, sensitization, intracutaneous reacivity, acute systemic toxicity, and material mediated pyrogenicity) included inappropriate materials, not representative of the patient contacting portions of you final device. Inclusion of these other materials may lead to a relative dilution of chemical leachants from your device, making biocompatibility testing results uninterpretable. Please repeat testing using just the Trek or Mini Trek catheter alone, and provide a complete test report. Alternatively, please provide a justification for including these other materials in your test extract, and why you believe the inclusion of these other materials would not affect the outcome of your results.

(b)(4)



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ATTACHMENT 3

Question 3:

For all biocompatibility tests, please clarify whether the extracts were filtered or otherwise manipulated after they were prepared. Please note that this information should be included in your final test reports.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ATTACHMENT 4

Question 4:

For cytotoxicity testing, please clarify how long after preparation the extracts were used.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8148.

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ATTACHMENT 5

Question 5:

Please address the following concerns regarding both your direct contact and extract hemolysis tests:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ATTACHMENT 6

Question 6:

For your complement activation testing, please provide a more detailed description of the test article, since the test article was only identified as "Xcalibur RX." Also, since it appears portions of the device was used to incubate in serum, please clarify which portions were used and why you believe the portions used were representative of the entire patient contacting portion of your device.

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ATTACHMENT 7

Question 7:

Please provide the following information regarding all color additives used in your device (with the exception of violet colorant used in the arm adapter, which is non-patient contacting):

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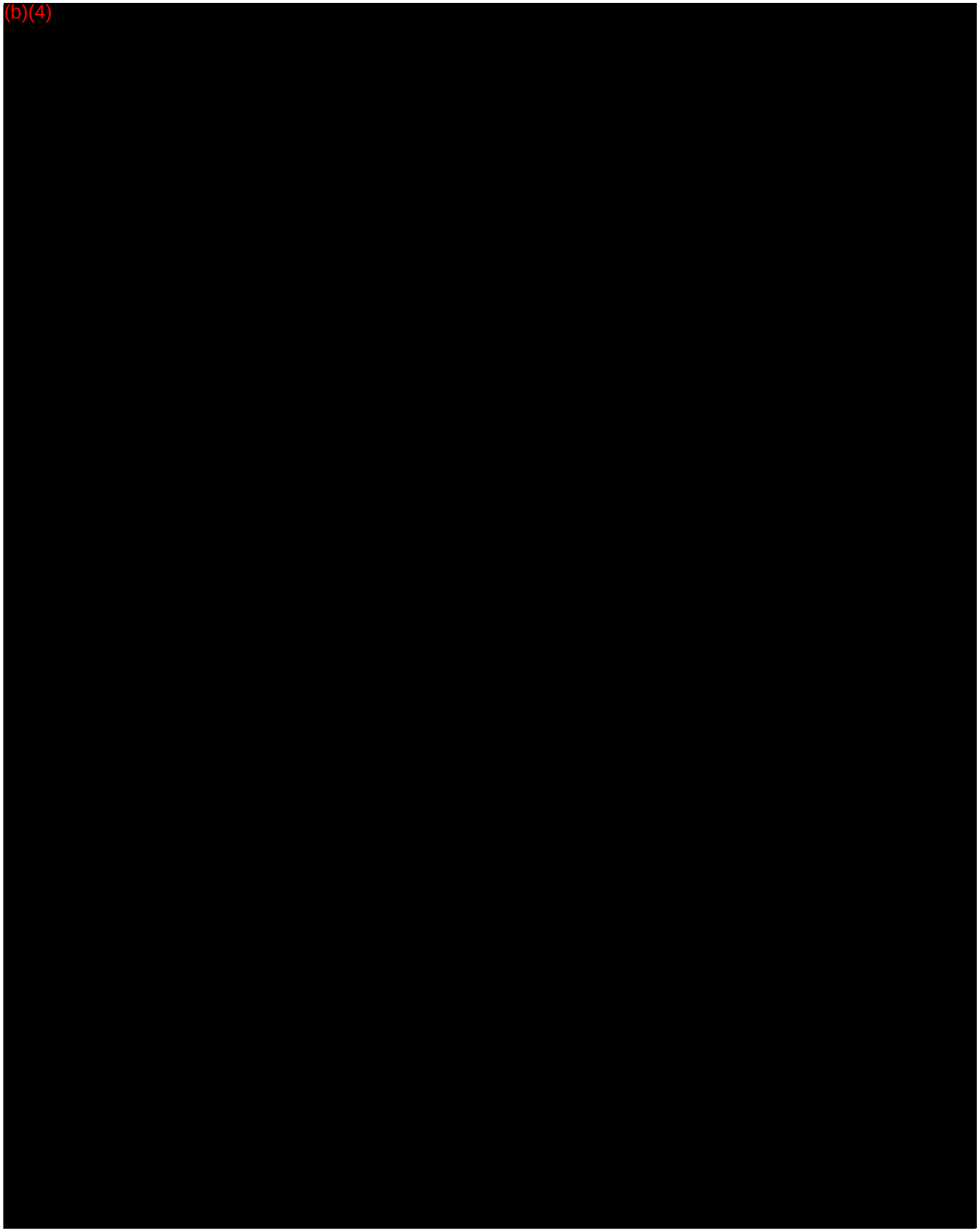
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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a. Chemical name and Chemical Abstract Services (CAS) number.

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

c. **Certification *that the color* additive is from a batch that does not need to be certified in accordance with the regulations issued under 706(c) for *that use* (*i.e.*, colors not requiring certifications are listed under 21 CFR 73 (Subpart D)). Color additives not exempt from the certification requirements are listed under 21 CFR 74 (Subpart D).**

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)



d. Specific amount of each color additive in the formulation by weight percent of the colored component and total amount (e.g., µg, ppm) in the device.

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)



Therefore, for all colorants with known amounts there are no anticipated adverse effects that would result from any of the colorants used in the TREK RX, MINI TREK RX, TREK OTW and MINI TREK OTW Coronary Dilation Catheters.

e. Material Safety Data Sheets (MSDSs) for each color additive.

(b)(4)



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Indirect Contact

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f. A risk assessment for each color additive, using toxicity information from the literature to include NOAEL, LOAEL, LD50, type of animal model, route of exposure, etc.

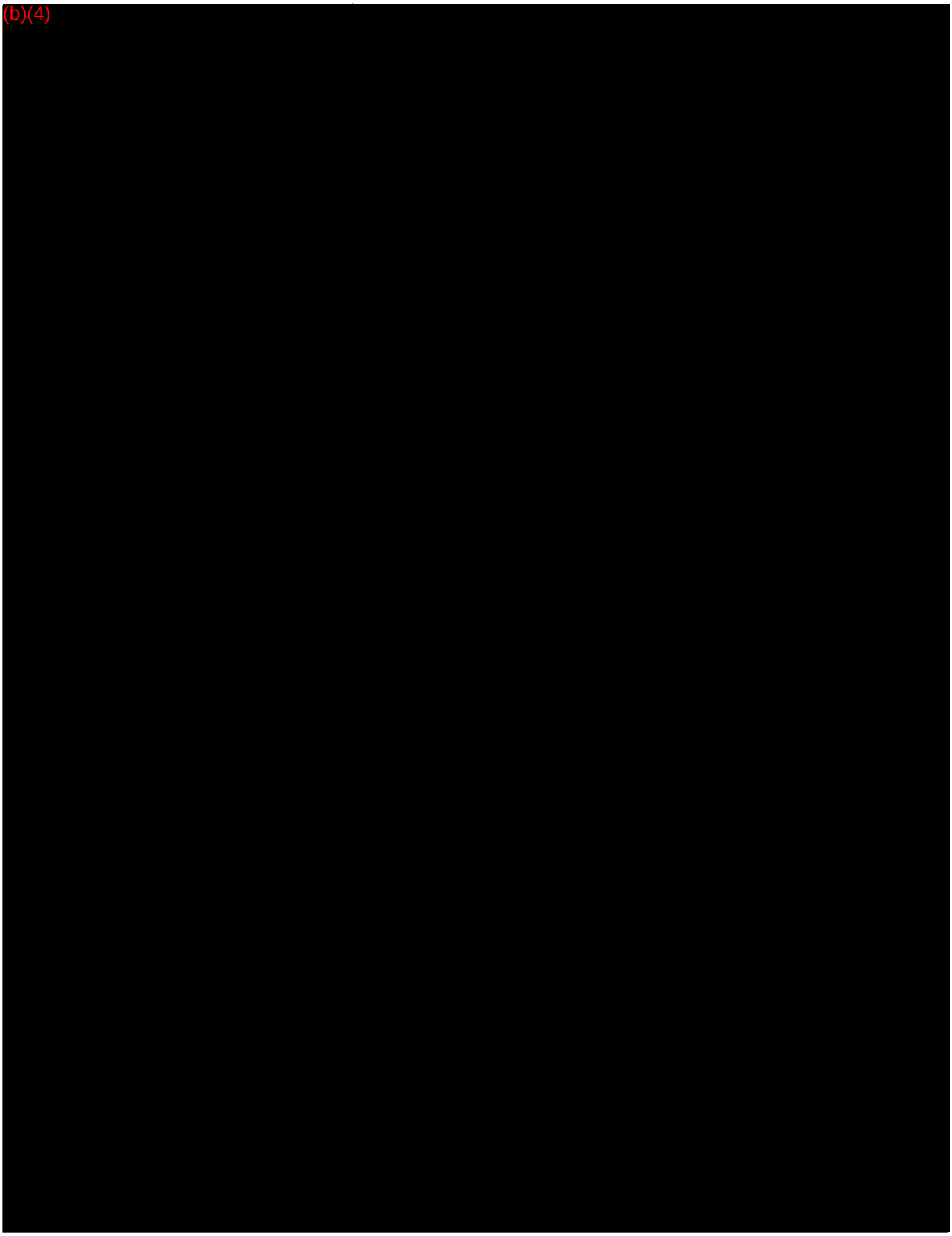
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g. **Data to demonstrate the amount of color additive eluted from the device over 30 days (or appropriate clinical worst case exposure plus a safety margin), to include:**

(b)(4)

[redacted]

h. **If the color additive "leaches" or elutes from the device, further assessments of the fate of the color additive in a relevant animal model (to include the timing of elimination, i.e., animal model evaluation as the product is intended to be used with pharmakokinetic type analysis, ADME study.**

(b)(4)

[redacted]

i. **If the color additive remains in the animal for greater than 30 days, then a CFSAN review of a color additive petition (CAP) would be necessary.**

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Meeting Minutes
Abbott Vascular and FDA Teleconference
Colorant Deficiencies – P810046/S235 and G100141
August 2, 2010

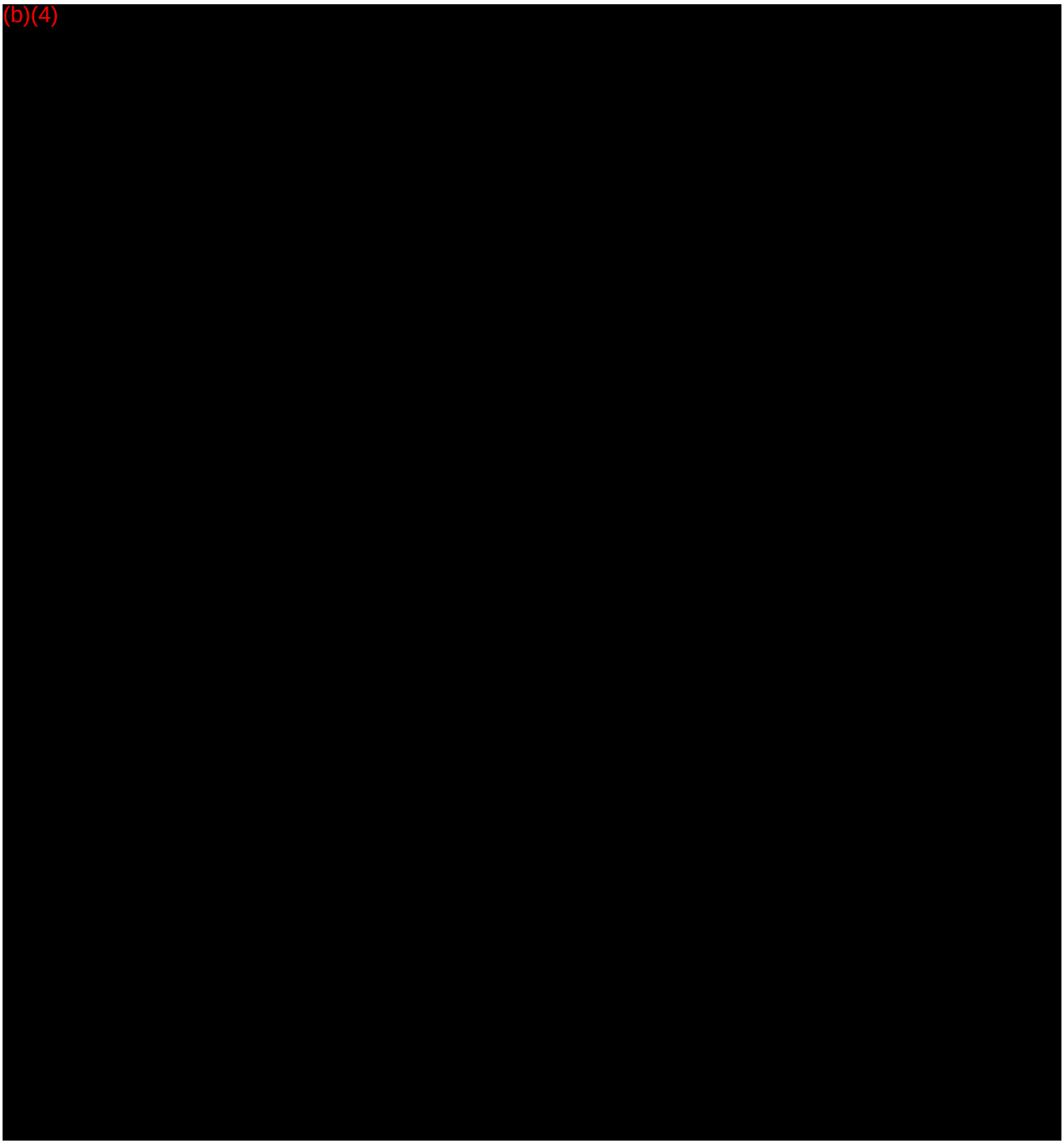
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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11 . Toxicological information

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

12 . Ecological information

Aquatic ecotoxicity

Conclusion/Summary : Not available.

Biodegradability

Conclusion/Summary : Not available.

13 . Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Refer to Section 7: HANDLING AND STORAGE and Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION for additional handling information and protection of employees.

14 . Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
DOT Classification	Not available.	Not available.	Not available.	-		-
TDG Classification	Not available.	Not available.	Not available.	-		-
Mexico Classification	Not available.	Not available.	Not available.	-		-
ADR/RID Class	Not available.	Not available.	Not available.	-		-
IMDG Class	Not available.	Not available.	Not available.	-		-
IATA-DGR Class	Not available.	Not available.	Not available.	-		-

PG* : Packing group

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15 . Regulatory information

HCS Classification : Not regulated.

U.S. Federal regulations : **United States inventory (TSCA 8b):** All components are listed or exempted.

SARA 302/304/311/312 extremely hazardous substances: No products were found.
SARA 302/304 emergency planning and notification: No products were found.
SARA 302/304/311/312 hazardous chemicals: No products were found.
SARA 311/312 MSDS distribution - chemical inventory - hazard identification: Fatty acids, montan-wax, 1-methyl-1,3-propanediyl esters: Immediate (acute) health hazard; 2,2'-[ethylenebis(oxyphenyl-2,1-eneazo)]bis[N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutyramide: Immediate (acute) health hazard

Clean Water Act (CWA) 307: No products were found.

Clean Water Act (CWA) 311: No products were found.

Clean Air Act (CAA) 112 accidental release prevention: No products were found.

Clean Air Act (CAA) 112 regulated flammable substances: No products were found.

Clean Air Act (CAA) 112 regulated toxic substances: No products were found.

Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

State regulations :

United States inventory (TSCA 8b) : *All components are listed or exempted.*

Canada inventory : All components are listed or exempted.

EU regulations

Risk phrases : This product is not classified according to EU legislation.

International regulations

International lists : **Australia inventory (AICS):** Not determined.
China inventory (IECSC): Not determined.
Japan inventory (ENCS): Not determined.
Japan inventory (ISHL): Not determined.
Korea inventory (KECI): Not determined.
New Zealand Inventory of Chemicals (NZIoC): Not determined.
Philippines inventory (PICCS): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

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16 . Other information

The customer is responsible for determining the PPE code for this material.

Date of printing	: **10/1/2009.**	
Date of issue	: 10/1/2009.	
Date of previous issue	: 4/7/2009.	
Version	: 0.02	Americhem 2 ISS MSDS North America (ANSI Z400.1) V4.0.5 - United States of America

▼ Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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Evaluation of Colorant Toxicity used in the TREK & MINI TREK (RX & OTW), Coronary Dilation Catheters

Prepared by
Heather E. Ferguson, Ph.D.
Global Occupational Toxicology, Abbott Laboratories
September 13, 20010

Appendix A7-8

Overall evaluation of colorant Toxicity used in the TREK/MINI TREK (RX/OTW) devices (including exhaustive bibliographic search)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Overview and Summary

The TREK and MINI TREK (RX and OTW) are PTCA Catheters intended for use in the treatment of coronary artery disease. The catheter chassis materials and manufacturing processes are identical for all balloon sizes comprised within a chassis. While the TREK family of PTCA catheters utilizes two different chassis (RX & OTW), as shown in the table below, each of these dilation catheters share identical pigments for those components of the catheters which are identical between RX and OTW, while others are specific to the chassis.

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Based on the available toxicity data for each of the pigments, the worst case exposure levels of each pigment, and the worst case length of possible time a patient is exposed to these pigments, there are no anticipated adverse health effects. All safety margins are calculated based on a 70 kg human. Also this risk assessment is based on the assumption (worst case) that all of the pigment leaches out into the patient during the acute exposure, which is highly unlikely.

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September 13, 20010

Background

Abbott Vascular received a deficiency letter from the FDA on August 9, 2010 indicating that the approval for the TREK and MINI TREK devices had been delayed pending more information in relation to FDA 21 CFR for adulteration of medical devices with pigments. The major concerns of the FDA in regards to the pigments found within the TREK and MINI TREK devices are with the leaching of the pigments and their carcinogenic potential, especially when the pigment has not been used previously in an Abbott Vascular device or is not approved by the FDA for alternative uses. Below is a risk assessment based on the available toxicity information related to each pigment. The majority of these pigments have not been studied for toxicity endpoints, and the data that exist are extremely limited. Some data by structural analogy is available, and where applicable has been applied. None of these pigments have existing data for short-term use in cardiovascular devices or intravenous injection.

Patient Contact Pigments

Yellow 180 – CAS# 77804-81-0

This yellow pigment does not have significant toxicity data. There are no studies within the literature that can be used to reference data for skin, eye or respiratory irritation, however due to the molecular structure and size of the molecule it is unlikely to be an irritant during coronary exposure, pigment dust could be irritating to the eyes and sensitive skin. Yellow 180 has not been investigated for carcinogenicity or genotoxicity in animals and no clinical human data related to carcinogenicity in adults, children, pregnant or elderly populations could be located. An oral study in rats was completed and the LD50 (lethal dose to 50% of the studied population) value was found to be greater than the highest dose tested, or 2,000 mg/kg. There is less than 8 micrograms of Yellow 180 used in each device. Though intravenous, subcutaneous, or intraperitoneal data would be more applicable for determining the risk of coronary exposure it is not available. The safety margin related to the equivalent lethal dose in humans compared to the rat LD50 would be greater than 17 million fold below this dose. There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral exposure, however since this data is not available the large safety margin related to the oral exposure in rats is likely sufficient to protect humans exposed during coronary artery dilation. The section of the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration. During this time it is not predicted that the Yellow 180 pigment will leach out of the device, therefore it will not remain in the patient long term. Based on the above information the Yellow 180 found in the TREK

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and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Orange 64 – CAS# 72102-84-2

This orange pigment has limited toxicity data. Based on structural analogy and the nitrogen moieties within the structure this pigment may cause skin or eye irritation, especially in sensitive individuals and in powdered form. There are no studies within the literature that can be used to reference data for skin, eye or respiratory irritation. Orange 64 has not been investigated for carcinogenicity or genotoxicity in animals and no clinical human data related to carcinogenicity in adults, children, pregnant or elderly populations could be located. An oral study in rats was completed and the LD50 value was found to be greater than 5,000 mg/kg. There is less than 6 micrograms of Orange 64 used in each device. Though intravenous, subcutaneous, or intraperitoneal data would be more applicable for determining the risk of coronary exposure it is not available. The safety margin related to the equivalent lethal dose in humans compared to the rat LD50 would be greater than 58-million-fold below this dose. There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral exposure, however since this data is not available the large safety margin related to the oral exposure in rats is likely sufficient to protect humans exposed during coronary artery dilation. The section of the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration. During this time it is not predicted that the Orange 64 pigment will leach out of the device, therefore it will not remain in the patient long term. Based on the above information the Orange 64 used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Red 144 – CAS# 5280-78-4

This red pigment has limited toxicity data. There are no studies within the literature that can be used to reference data for skin, eye or respiratory irritation, however due to the molecular structure and size of the molecule it is unlikely to be an irritant during coronary exposure, pigment dust could be irritating to the eyes and sensitive skin. Red 144 has not been investigated for carcinogenicity or genotoxicity in animals and no clinical human data related to carcinogenicity in adults, children, pregnant or elderly populations could be located. An oral study in rats was completed and the LD50 value was found to be greater than 5,000 mg/kg. There is less than 0.4 micrograms of Red 144 used in each device. Though intravenous, subcutaneous, or intraperitoneal data would be more applicable for determining the risk of coronary exposure it is not available. The safety margin related to the equivalent lethal dose in humans compared to the rat LD50

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would be greater than 875- million fold below this dose. There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral exposure, however since this data is not available the large safety margin related to the oral exposure in rats is likely sufficient to protect humans exposed during coronary artery dilation. The section of the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration. During this time it is not predicted that the Red 144 pigment will leach out of the device, therefore it will not remain in the patient long term. Based on the above information the Red 144 used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Violet 23 - CAS#6358-30-1

This violet pigment has limited toxicity data. There are no studies within the literature that can be used to reference data for skin, eye or respiratory irritation, however due to the molecular structure and size of the molecule it is unlikely to be an irritant during coronary exposure, pigment dust could be irritating to the eyes and sensitive skin. Violet 23 has not been investigated for carcinogenicity or genotoxicity in animals and no clinical human data related to carcinogenicity in adults, children, pregnant or elderly populations could be located. An oral study in rats was completed and the LD50 value was found to be 5,000 mg/kg. There is less than 36 micrograms of Violet 23 used in each device. Though intravenous, subcutaneous, or intraperitoneal data would be more applicable for determining the risk of coronary exposure it is not available. The safety margin related to the equivalent lethal dose in humans compared to the rat LD50 would be greater than 9.5- million fold below this dose. There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral exposure, however since this data is not available the large safety margin related to the oral exposure in rats is likely sufficient to protect humans exposed during coronary artery dilation. The section of the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration. During this time it is not predicted that the Violet 23 pigment will leach out of the device, therefore it will not remain in the patient long term. Based on the above information the Violet 23 used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Carbon Black – CAS# 1333-86-4

Carbon black is used as a pigment in many applications from toner cartridge ink to packaging and labeling. Powdered carbon black is a respiratory and eye irritant, with the potential to be a skin irritant to sensitive individuals. However, no data could be located on irritation related to coronary exposure or skin exposure to Carbon Black in the same form as is used in the TREK and MINI TREK devices. Carbon Black is categorized as a Group 2B possible human carcinogen. This classification indicates that there is sufficient data in animals to determine carcinogenic risk, but not conclusive evidence in humans.

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There have been numerous epidemiology studies which have failed to indicate an increased risk of lung cancer from occupational exposure to carbon black. Carbon black has not been shown in mice (oral, skin or inhalation), hamsters (inhalation or intratracheal aspiration), guinea pigs (inhalation), rabbits (skin or inhalation), primate (skin or inhalation) or rats (oral) to be carcinogenic. Only studies in rats using inhalation or intratraceal aspiration methods have indicated an increase in keratinizing squamous-cell tumors (malignant and benign). These tumors do not occur in humans. Additionally, an epidemiological review of the data between the time IARC reclassified carbon black from a Group 3 to a Group 2B indicates that there is inadequate data to suggest that carbon black is a human carcinogen and limited data that it is an animal carcinogen. The rat inhalation studies that have been completed use high doses of carbon black inhalation, over an extended (days) period of time. None of the studies using carbon black and looking at carcinogenicity resulted from a single, low dose exposure. Human disease related to carbon black exposure has been related to long term occupational exposure, resulting in particulate related disease similar to exposure from other particulates – fibrosis. There are no data and there are no studies in humans or animals that indicate short term (acute – single dose) coronary exposure results in long term health effects. Many studies related to genotoxicity have been completed. The conclusion from these studies is that carbon black is not considered genotoxic. The only acute single dose toxicity information that is available is related to the lethal dose in rats, and is therefore the only acute indicator of toxicity available. An oral study in rats was completed and the LD50 value was found to be greater than 3,000 mg/kg. There is less than 30 micrograms of carbon black used on each device. Though intravenous, subcutaneous, or intraperitoneal data would be more applicable for determining the risk of coronary exposure and toxicity, it is not available. The safety margin related to the equivalent lethal dose in humans compared to the rat LD50 would be greater than 7- million fold below this dose. There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral exposure, however since this data is not available the large safety margin related to the oral exposure in rats is likely sufficient to protect humans exposed during coronary artery dilation. The section of the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration. During this time it is not predicted that the carbon black will leach off the device, therefore it will not remain in the patient long term. Based on the above information the carbon black used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Non-Patient Contact

Violet 15 – CAS# 12769-96-9 <1.6 mg/ device

This violet pigment has very limited toxicity data. There are no studies within the literature that can be used to reference data for skin, eye or respiratory irritation, however

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due to the molecular structure and size of the molecule it is unlikely to be an irritant during coronary exposure, pigment dust could be irritating to the eyes and sensitive skin. Violet 15 has not been investigated for carcinogenicity or genotoxicity in animals and there is no clinical human data related to carcinogenicity in adults, children, pregnant or elderly populations. An oral study in rats was completed and the LD50 value was found to be greater than 10 grams /kg. The amount of Violet 15 used in each device is less than 1.6 mg/device. Therefore, there is a greater than 430,000-fold safety margin between the equivalent human LD50 value.This pigment is not in direct contact with the patient, there is no evidence of pigment transfer, and there are manufacture controls which prevent these pigments being transferred during manufacture. There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral exposure, however since the colorant does not have patient blood contact, the procedure which uses the TREK or MINI TREK device is short (usually 10 minutes, and up to 1 hour), and the LD50 value is very high (10 grams), therefore the risk is very low for adverse effects during/post coronary artery dilation using the TREK or MINI TREK. Based on the above information the Violet 15 used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Blue 29 – CAS# 57455-37-5

This blue pigment has some toxicity data. There are no studies within the literature that can be used to reference data for skin, eye or respiratory irritation, however due to the molecular structure and size of the molecule it is unlikely to be an irritant. Blue 29 has not been investigated for carcinogenicity or genotoxicity in animals and there is no clinical human data related to carcinogenicity in adults, children, pregnant or elderly populations. An acute dose oral study in rats was completed and the LD50 value was found to be greater than 2,000 mg/kg. Additionally, repeated dose, reproductive/ developmental toxicity studies were completed in rats following the OECD guideline 422. The rats were given Blue 29 via the oral route at doses up to 1000 mg/kg/day for 42 days in males and 14 days premating through 4 days of lactation in females. The NOAEL for repeated dose study was 300 mg/kg due to slight squamous cell hyperplasia in the stomach of the rats in both sexes. There were no alterations in reproductive or developmental parameters. The NOAEL for reproductive/developmental endpoint was 1000 mg/kg/day. The amount of Violet 15 used in each device is less than 80 micrograms, therefore there is a greater than 260,000-fold safety margin between the equivalent human NOAEL (for squamous cell hyperplasia endpoints, for a 70-kg human) value compared to the amount that could be found in the device. This pigment is not in direct contact with the patient, there is no evidence of pigment transfer, and there are manufacturing controls which prevent these pigments being transferred during manufacture. Though intravenous, subcutaneous, or intraperitoneal data would be more applicable for determining the risk of coronary exposure it is not available. The safety

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margin related to the dose which caused squamous cell hyperplasia in the stomach of rats (300 mg/kg - which is equivalent to 21 grams/day for a 70-kg human) would be far greater than the amount that could be present in the device. There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral exposure, however since the pigment does not have patient contact, and the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration, the risk is very low for adverse effects during/post coronary artery dilation using the TREK or MINI TREK. Based on the above information the Blue 29 used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Titanium Dioxide – CAS# 13463-67-7

Titanium dioxide has many applications in products used by humans, including sunscreen, pigment, food and medical devices. It is currently FDA approved for use in food items (less than 1% by weight), for coloring internally ingested and externally applied pharmaceuticals (following GMP guidelines) and may be used in cosmetics and contact lenses (amounts not to exceed the minimum needed to obtain indented coloring effect). Titanium dioxide powder has been investigated as an irritant of the eyes, skin and respiratory tract. As a colorant in a medical device titanium dioxide is not in the powdered form and there are no studies within the literature that can be used to evaluate the potential for skin, eye or respiratory irritation. However, based on the use of titanium dioxide as a colorant in contact lenses which can be worn for 8 hours up to continual wear there is no evidence this material should be irritating to the eyes or skin of the general population who could be exposed through the use of the TREK or MINI TREK devices. There has been significant research into the genotoxic potential of titanium dioxide in the standard battery of genotoxicity testing (Ames, mouse micronucleus, mouse lymphoma and chromosomal aberration), all of these tests were negative. Additionally, carcinogenicity has been investigated in mice and rats. IARC has also reviewed this material. Based on the available evidence inhalation of titanium dioxide powder may pose an increased risk for carcinogenicity in humans. However, oral exposure does not pose the same risk of carcinogenicity based on rodent inhalation exposure. Titanium dioxide represents a category 2B risk of carcinogenicity. There are no studies which evaluate carcinogenicity based on acute low dose exposure. The studies used the inhalation route and doses (0-250 mg/m3) were given for 6 hours, 5 days a week for time periods greater than 1 year, variations on the dosing regimen have been used. The risk for cancer in rodents is evident based on chronic exposure to titanium dioxide. However, based on the level and length of possible exposure time to titanium dioxide through the use of the TREK and MINI TREK devices there is limited risk of harm to the potential patients from these devices. There are current standards for worker exposure to titanium oxide which include the TLV of 10 mg/m3 or 100 mg/8 hour work day, the OSHA PEL is 15 mg/m3 (150 mg/8 hour day) of total dust and the NIOSH control of

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5,000 mg/m3 (50,000mg/8 hour day). The oral ALD in the rat is greater than 24 grams, the inhalation ALC in the rat is greater than 6.82 mg/L, the dermal LD50 in the rabbit is greater than 10 grams. The TREK and MINI TREK device has no more than 21 mg in the device, and it does not have direct blood contact. This pigment is not in direct contact with the patient, there is no evidence of pigment transfer, and there are manufacturing controls which prevent these pigments being transferred during manufacture. Therefore, the level of exposure (if all of the titanium dioxide were to leach out of the device) is significantly lower than the amount that causes harm by oral or dermal exposure (greater than 400-fold less). There are different pharmacokinetics and pharmacodynamics related to coronary exposure compared to oral and dermal exposure, however since this data is not available the large safety margin related to the oral and dermal exposure in rats and rabbits is likely sufficient to protect humans exposed during coronary artery dilation. The section of the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration. During this time it is not predicted that the titanium dioxide pigment will leach out of the device, therefore it will not remain in the patient long term. Based on the above information the titanium dioxide used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

Ferric Oxide – CAS# 1309-37-1

Ferric oxide is used in several applications in steel, as a polishing agent, and as a pigment under the names Pigment Brown 6 or 7 and Pigment Red 101. Iron dust or fumes can cause a benign pneumoconiosis after a prolonged exposure to high levels. However there is no evidence of iron oxide causing fibrotic changes, but recent animal studies have shown a mild inflammatory response, when inhaled. Iron oxide is negative in Ames assays for mutagenicity. Ferric oxide is an IARC Group 3 substance, which indicates that there is inadequate evidence that it is a human carcinogen and there is a lack of evidence to suggest it is a carcinogen in animals. The ACGIH rating is an A4 substance, indicating that it is not classifiable as a human carcinogen. Ingestion of less than 20 mg/kg of elemental iron (140 mg) is generally regarded as safe. There are no studies within the literature that can be used to reference data for skin, eye or respiratory irritation, however it is unlikely to be an irritant during coronary exposure, pigment dust could be mechanically irritating to the eyes and sensitive skin. The LDLo value in dogs after subcutaneous injection is 30 mg/kg (2100 mg in a 70 kg human). The level of ferric oxide (alone) present in the device is not known. This pigment is not in direct contact with the patient, there is no evidence of pigment transfer, and there are manufacturing controls which prevent these pigments being transferred during manufacture. The amount that is necessary to cause significant harm is very high compared to the amount that is possible to be present in the device, additionally since the pigment does not have patient contact, and the procedure which uses the TREK or MINI TREK device is commonly 10 minutes (up to 1 hour) in duration, the risk is very low for adverse effects during/post coronary artery dilation using the TREK or MINI TREK. Based on the above information the

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ferric oxide used in the TREK and MINI TREK devices is not likely to cause short or long term adverse effects to a patient.

References

1. Emails from J. Duchamp received August 2010.
2. MSDS for TP300/N50 C-MIX 2000 Schwarz – Coates Screen – Carbon Black colorant.
3. Carbon Black (133-86-4) - ChemIDplus Lite – United States National Library of Medicine – Online Edition 2010.
4. Carbon Black (133-86-4) - Hazardous Substance Data Base – United States National Library of Medicine – Online edition 2010.
5. MSDS – 11-3073 PV Fast Yellow HG (77804-81-0) – Clariant Corporation – Revised 07/27/2009.
6. MSDS – Cromophtal Orange GP (72102-84-2) – BASF – Revised 07/05/2010
7. MSDS – Cromopthal Red Brown (5280-78-4) – Ciba – Revised 12/10/2003
8. MSDS – 6333 Purple Concentrate – Clariant Corporation – Revised 08/13/2010
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Appendix A7-9

Color Additives Used in the TREK/MINI TREK (RX/OTW) for all components that are in DIRECT and INDIRECT Patient Contact

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Manufacturing & Quality Risk Assessment

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Manufacturing Assessment

An assessment of the manufacturing processes of the TREK/MINI TREK RX and TREK/MINI TREK OTW CDCs was performed to verify that the catheter components are not exposed to additional colorant pigments during normal manufacturing conditions and that the components containing the color additives do not "rub off" or leach their pigments onto other sections of the device.

Manufacturing Controls

The manufacturing processes for the TREK family of Coronary Dilatation Catheters contain in-process controls to prevent the inadvertent inclusion of contaminants, including colorants used on other components of the device, to the device. These controls include tooling, equipment and inspections.

The tooling aids that come in contact with the catheter during manufacturing contain no transferable colorants. Examples include:

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(b)(4) **come in direct contact with the device are free of colorants**.

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After each operation, an in-process visual inspection is conducted to ensure no contaminants are present on the subassembly. Each catheter is 100% visually inspected at multiple stations.

Conclusion:

There are no components identified that could potentially introduce unintended colorant pigments to other components of the device during manufacturing processing.

Pigment Transfer

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The manufacturing processes of the components that contain color additives were reviewed to ensure that no transfer of the colorant occurs during manufacturing/packaging processes that could cause subsequent colorant transfer to of unintended sections of the catheter.

There have been no recorded instances of colorant transfer during manufacturing operations as the processing of the components is performed under manufacturing parameters that do not offer conditions for the colorant to transfer from their encapsulated states within the device components. Components containing colorants are mechanically processed with no chemical breakdown of the pigmented polymers.

After each operation, the sub-assemblies are inspected to ensure that there are no foreign materials present. Once the catheters are fully assembled and packaged, a Quality Control sampling is performed for each lot wherein units are inspected post-packaging to ensure there are no contaminants present, including those that may have been introduced by the packaging components.

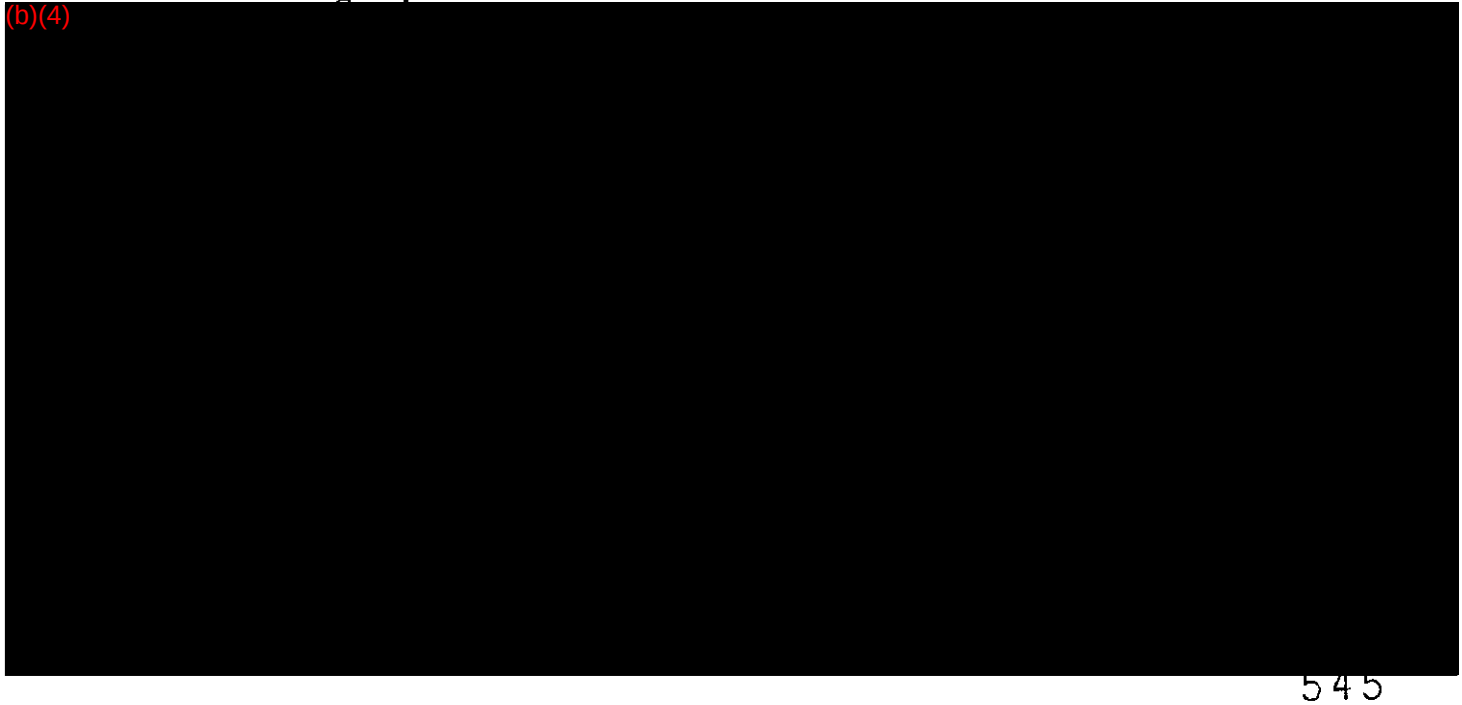
In addition, pre- and post-sterile testing of fully processed units, including all final packaging components are visually inspected, with no instances of colorant transfer between catheter and/or packaging components.

Conclusion:

Based on Abbott Vascular's Manufacturing and Quality inspection controls as well as the nature of the materials within which the colorants are impregnated, there are no identified circumstances under which components using color additives could potentially be transferred from one part of the device to another.

Detailed Processing Steps

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The four corners testing for Balloon Fatigue within a Stent included the shortest and longest balloon lengths of the following diameters:

- MINI TREK RX: 2.00 mm
- TREK RX: 2.25 mm, 4.00 mm and 5.00 mm

The table below shows the full size matrix for the MINI TREK RX and TREK RX with the corner sizes highlighted in yellow.

Table A12-1 Size Matrix Corner Sizes

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK RX Coronary Dilatation Catheter							
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X
TREK RX Coronary Dilatation Catheter							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50			X	X			
5.00			X	X			

The rationale behind the device sizes selected for post-aged testing of balloon output was based on the scientific justification detailed as follows:

For aged sample testing, an engineering study preceding the selection of the post-aged sizes to be tested for balloon outputs was performed to identify actual worst-case balloon diameters for each balloon design, MINI TREK (single layer, 1.50 mm – 2.00 mm) and TREK (co-extruded, 2.25 mm – 5.00 mm), to be tested for post-aged balloon outputs.

This study evaluated balloon fatigue and balloon rupture for the shortest and longest lengths of each balloon diameter. The shortest and longest lengths within each diameter were pooled for analysis. A minimum of 30 samples per diameter were evaluated. The study results showed that all fatigue testing passed the confidence and reliability requirement for attribute data, therefore, no definable worst case size was determined. However, a low RBP would be indicative of the relative weakness that a particular balloon diameter would have compared to other balloon diameters for balloon outputs. Theoretically, this relative weakness can be translated to a lower fatigue performance, and thus, the sizes that exhibited the lower rupture values were selected to represent the

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worst case for fatigue. For this reason, a representative balloon size was chosen for each balloon design, MINI TREK RX and TREK RX, based on the balloon diameters with the lowest calculated rated burst pressure (RBP).

As part of this engineering study, all diameters and shortest and longest lengths of each balloon design were built and tested for balloon rupture. The shortest and longest lengths within each diameter were pooled for analysis. A minimum of 30 samples per diameter were evaluated. A summary of the Rupture data is provided in **Table A12-2**.

Table A12-2 Worst Case Balloon Rupture Data Summary

Balloon Design	Diameter (mm)	Average (StDev)	RBP
MINI TREK	1.50	330 psi (17.0)	265 psi
MINI TREK	2.00	331 psi (12.6)	286 psi
TREK	2.25	332 psi (13.3)	285 psi
TREK	2.50	347 psi (19.5)	278 psi
TREK	2.75	317 psi (21.1)	242 psi
TREK	3.00	322 psi (11.7)	277 psi
TREK	3.25	363 psi (13.6)	311 psi
TREK	3.50	329 psi (11.2)	286 psi
TREK	3.75	337 psi (15.0)	279 psi
TREK	4.00	332 psi (15.3)	274 psi
TREK	4.50	340 psi (10.4)	301 psi
TREK	5.00	321 psi (12.8)	273 psi

While each size met the required specification, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters. Based on the results of this testing, it was demonstrated that the 1.50 mm and the 2.75 mm diameters represented the worst-case sizes for single layer and co-extruded balloons respectively. Since the proposed indication associated with post-stent dilatation is applicable only to the 2.00 mm through 5.00 mm balloon diameters, the 2.00 mm size was selected as representative for the single layer size.

Therefore, the sizes selected for post-aged testing of balloon fatigue within a stent were determined in accordance with the FDA's *Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* which states that if testing is not conducted according to the four corners paradigm, a scientific rationale to support the sizes that

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were tested, along with an analysis to identify the size or sizes that represent the worst case can be used. Abbott Vascular believes that the sizes selected for post-aged balloon fatigue within a stent; namely 2.00 mm and 2.75 mm, are compliant with the FDA guidance and therefore, are representative of the MINI TREK and TREK balloon size matrix when tested for balloon fatigue within a stent.

At baseline testing, the 5.00 mm x 12 mm had two samples which did not achieve the required 10 cycles for Balloon Fatigue Within a Stent testing. An additional 29 samples were added to the to the Balloon Fatigue Within a Stent testing, which satisfied the requirement of 10 repeated inflations with 95% confidence and 90% reliability. Since the 5.00 x 12 mm met the fatigue requirement for within a stent, the original worst case size selection is still valid.

The response included in this attachment is also applicable to the TREK OTW and MINI TREK OTW. The balloons for both the OTW and RX catheter systems are identical; therefore, testing of one catheter system for Balloon Fatigue within a Stent is representative of the other catheter system.

c. Please clarify what size stents were used for each balloon size tested.

For the 2.00 mm through 4.00 mm sizes, the MULTI-LINK 8 stent was used for Balloon Fatigue within a Stent testing. For the larger balloon sizes, the 4.50 mm through 5.00 mm, the MULTI-LINK ULTRA stent was used.

Table A12-3 – Stents Used for "Within a Stent" Testing

Balloon Diameter	Stent Used in Testing
2.00 mm – 3.25 mm	MULTI-LINK 8, P020047/S017, approved 6/22/2010
3.50 mm – 4.00 mm	MULTI-LINK 8, P020047/S017, approved 6/22/2010
4.50 mm – 5.00 mm	MULTI-LINK ULTRA, P970020/S021, approved 9/8/2000

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Table A13-1 Worst Case Balloon Rupture Data Summary

Balloon Design	Diameter (mm)	Average (StDev)	RBP
MINI TREK	1.50	330 psi (17.0)	265 psi
MINI TREK	2.00	331 psi (12.6)	286 psi
TREK	2.25	332 psi (13.3)	285 psi
TREK	2.50	347 psi (19.5)	278 psi
TREK	2.75	317 psi (21.1)	242 psi
TREK	3.00	322 psi (11.7)	277 psi
TREK	3.25	363 psi (13.6)	311 psi
TREK	3.50	329 psi (11.2)	286 psi
TREK	3.75	337 psi (15.0)	279 psi
TREK	4.00	332 psi (15.3)	274 psi
TREK	4.50	340 psi (10.4)	301 psi
TREK	5.00	321 psi (12.8)	273 psi

While each size met required specifications, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters. Based on the results of this testing, it was demonstrated that the 1.50 mm and the 2.75 mm diameters represented the worst-case sizes for single layer and co-extruded balloons respectively. A low RBP would be indicative of the relative weakness that a particular balloon diameter would have compared to other balloon diameters for balloon outputs.

The engineering study also made provision for lot-to-lot variation and potential statistical aberration (which are inherent to any balloon design) that could occur during baseline testing. Abbott Vascular acknowledges that the baseline data may give the appearance that the 2.00 mm x 30 mm and the 5.00 mm x 15 mm represent worst case sizes. However, based on the conclusions presented in the preceding body of data, this anomaly can be attributed to lot-to-lot variation and does not invalidate the original conclusion that the 1.50 mm and the 2.75 mm diameters represent the worst-case sizes for single layer and co-extruded balloons respectively, when tested for balloon outputs.

Therefore, the sizes selected for post-aged testing of balloon outputs were determined in accordance with the FDA's *Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* which states that if testing is not conducted according to the four corners paradigm, a scientific rationale to support the sizes that were tested, along with an analysis to

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identify the size or sizes that represent the worst case can be used. Abbott Vascular believes that the sizes selected for post-aged balloon output, 1.50 mm x 20 mm and 2.75 mm x 30 mm, are compliant with the FDA guidance and therefore, are representative of the MINI TREK and TREK balloon size matrix when tested for balloon output.

Figure A13-1 and **Figure A13-2** provide a statistical analysis of balloon rupture data between baseline and aged samples for the 1.50 x 20 mm and 2.75 x 30 mm sizes. Data were analyzed using JMP 8.0 software.

For the 1.50 mm x 20 mm, the analysis shows a statistically significant difference in means. The aged samples demonstrate a higher average rupture than the baseline samples. All baseline and aged units meet the finished product specification of 206 psi (14 atm) minimum at 95% confidence / 99.9% reliability.

For the 2.75 mm x 30 mm, the analysis shows a statistically significant difference in means. The aged samples demonstrate a lower mean rupture than the baseline samples. All baseline and aged units meet the finished product specification of 206 psi (14 atm) minimum at 95% confidence / 99.9% reliability.

The differences between the aged and baseline results are attributed to lot-to-lot variation due to material and manufacturing equipment. At the balloon blow operation, the balloons must meet a more stringent in-process rupture (psi) specification when compared to the product specification. The set up rupture specifications are diameter specific and were based on confidence limits calculations established with rupture data generated at the balloon blow station.

- For the 1.50 mm balloon diameter, the balloon blow in-process rupture specification range is 353 psi minimum.

- For the 2.75 mm balloon diameter, the balloon blow in-process rupture specification range is 307 psi minimum.

Differences in rupture performance during set up at the balloon blow operation translate to differences in rupture performance in the Finished Device state (baseline and aged). The differences in the means for baseline and aged samples are therefore attributable to normal lot-to-lot variability expected in the manufacturing environment. As well, the differences in rupture when comparing baseline to aging remain above the minimum requirements established in the product specification. Therefore, it can be concluded that aging has no significant safety concern on balloon rupture performance.

The differences in rupture at baseline and aged are attributed to lot-to-lot variability. All baseline and aged units meet the finished product specification of 206 psi (14 atm) minimum at 95% confidence / 99.9% reliability and data are not indicative of a potential safety concern.

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ATTACHMENT 14

Question 14:

Please address the following concerns regarding Balloon Rupture Within a Stent

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ATTACHMENT 15

Question 15:
Please address the following concerns regarding your Balloon Compliance testing:

All responses included in this attachment are applicable to both the TREK OTW and MINI TREK OTW. The distal portions of the catheters, including the balloons, for both the OTW and RX delivery systems are identical, therefore, testing of one delivery system platform for Balloon Compliance is representative of the other delivery system platform

a. **The rationale behind the device sizes selected for post-aged testing was not clear. Please repeat Balloon Compliance using aged samples of all "corner sizes" for both the MINI TREK and TREK catheters or provide a scientific justification for the sizes used for post-aged samples.**

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b. **It appears that there are different numbers of samples tested at different inflation pressures, in some cases with an increase in sample number with increasing pressure. Please clarify why there are a different number of samples at different inflation pressures.**

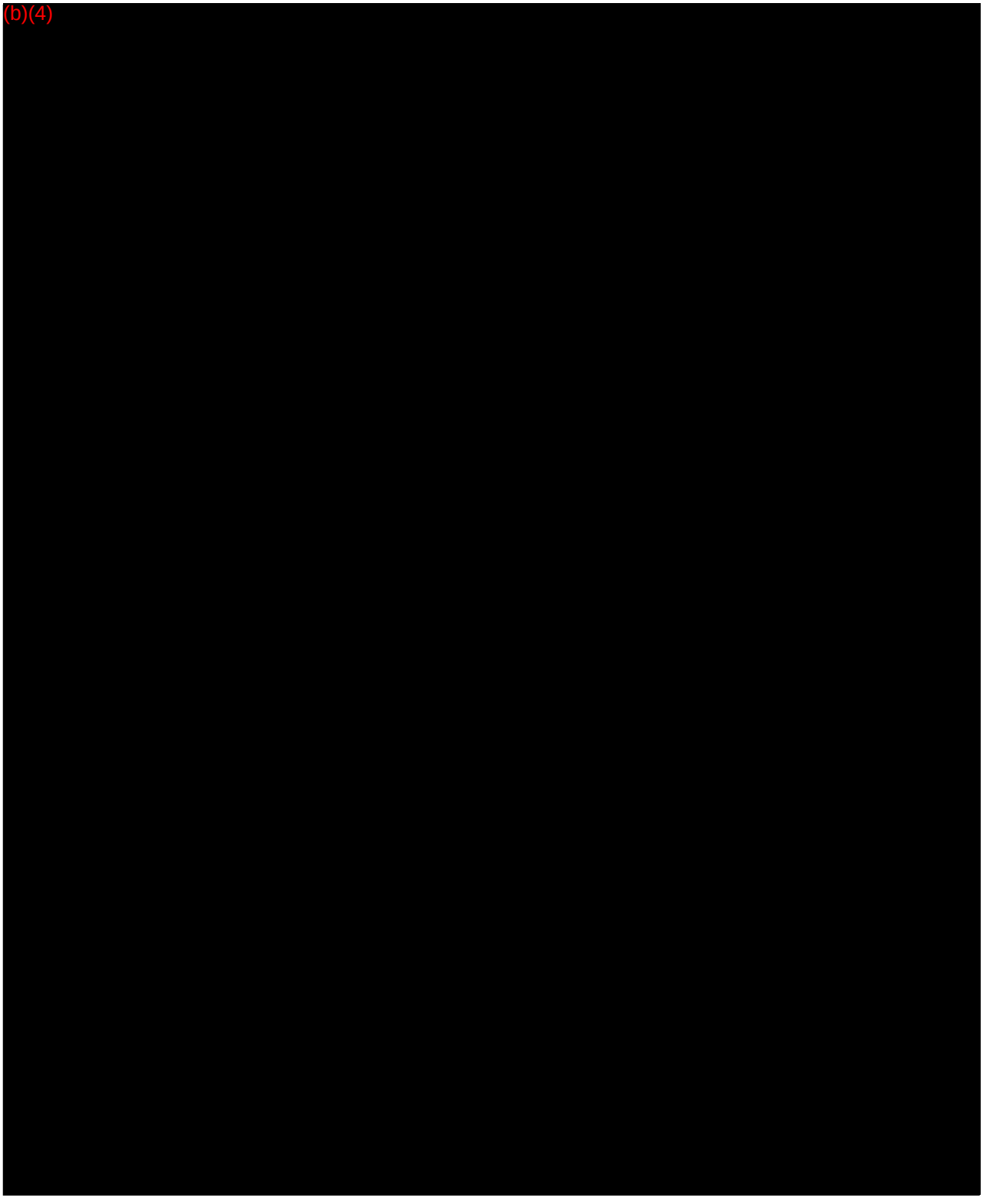
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c. Please provide a statistical comparison of balloon diameters at nominal and rated burst pressure between baseline and aged samples to demonstrate that aging has no significant effect on balloon compliance.

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ATTACHMENT 16

Question 16:

In your Distal Catheter Tensile (midlap seal) test, you did not perform a statistical analysis between aged and unaged samples. It appears that the TREK samples (5.0 mm x 15 mm and 2.25 mm x 30 mm) showed a substantial decrease in this property with aging, with a minimum strength of 1.5 lbs in one of the samples. Please provide a statistical comparison of the aged and unaged samples and provide a scientific rationale for why you believe the Distal Catheter Tensile Strength does not raise a safety concern.

(b)(4)



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ATTACHMENT 17

Question 17:

Please repeat Catheter Coating Particulates testing and address the following concerns in your repeated testing:

a. **It appears you have flushed your tortuous tracking fixture after the guidewire and guide catheter were placed in the fixture, and discarded the effluent. Since patients would be exposed to the particles generated from these accessory devices necessary for the use of your device, please collect the effluent and report the total particulate count for this effluent.**

(b)(4)



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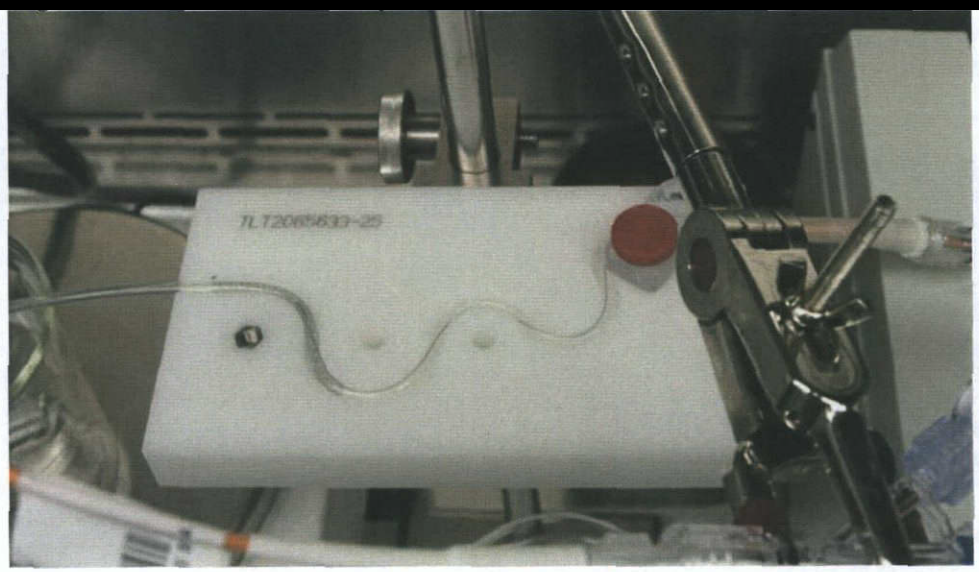
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b. It was unclear from the photograph of your tracking fixture, whether the whole catheter is tracked through the fixture, or if only a distal segment is inserted into the fixture. Please make sure that the fixture is sufficiently long such that the whole patient contacting parts of the catheter can be tracked into the fixture, and particulates generated from this entire length are captured. In addition, you did not provide the critical dimensions of your test fixture (radius of curvature, diameter of track, etc.). Nevertheless, your fixture appears to be less tortuous than the coronary artery model in ASTM F 2394-04 Fig x2.4, and lacks the aortic arch portion. Please revise your tracking fixture to match the dimensions in ASTM F 2394-04 Fig x2.4 or equivalent.

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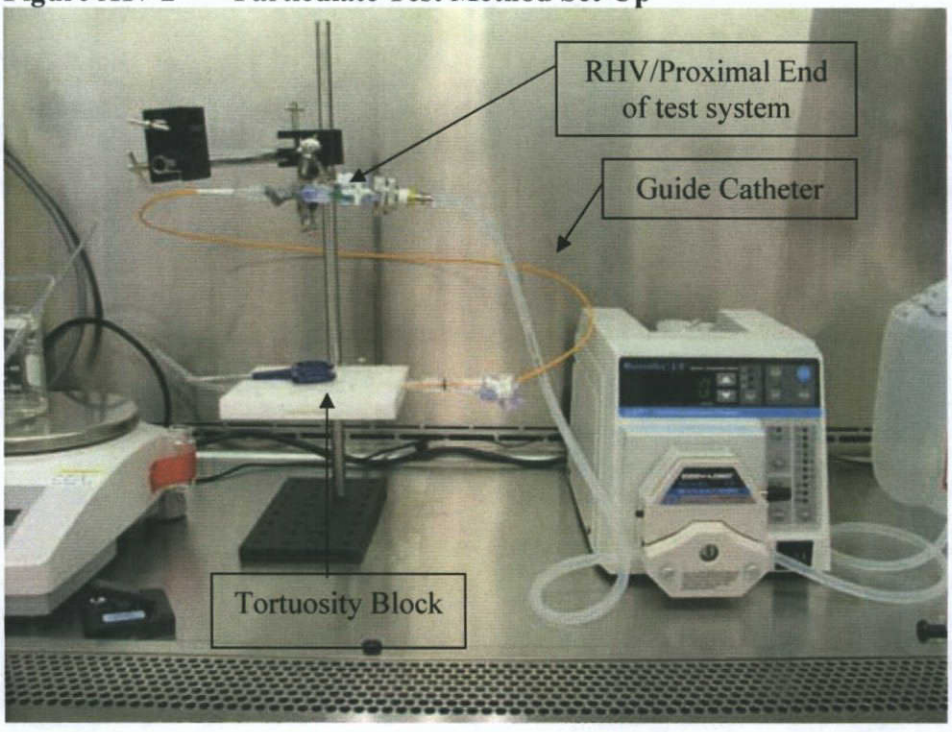
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Figure A17-2 shows the entire test set-up used during the particulate testing. The proximal end of the guide catheter is connected to a Rotating Hemostatic Valve (RHV) and is the location that the catheter enters the system. The catheter is inserted into the RHV and tracked the entire length of the guide catheter and into the fixture, simulating clinical use of the device. During testing approximately 130 cm of the catheter are located in the test system, which ensures that all patient contacting parts of the device enter the test system and are included in the particulate count.

Figure A17-2 Particulate Test Method Set-Up



Although the tortuosity block does not have a simulated aortic arch, the guide catheter is positioned so that there is a large bend, shown in **Figure A17-2**, subjecting the catheter to bend prior to entering the tortuosity block. Since this testing was performed, Abbott Vascular has developed an aortic arch fixture as shown in **Figure 17-3**, to be used in conjunction with the particulate tortuosity fixtures. A detailed view of this fixture is shown in **Figure A17-4**.

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Figure A17-3 Tortuousity Block with Aortic Arch Fixture

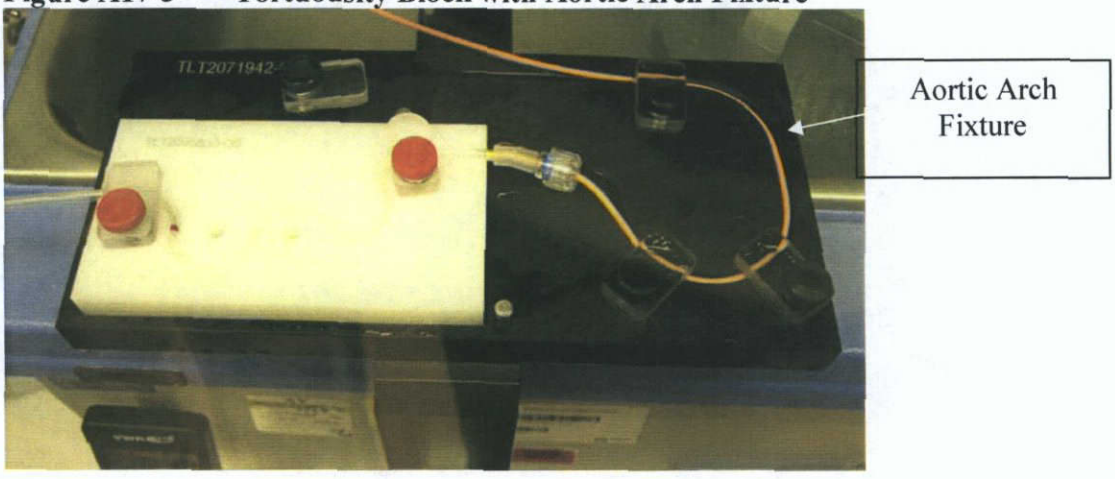
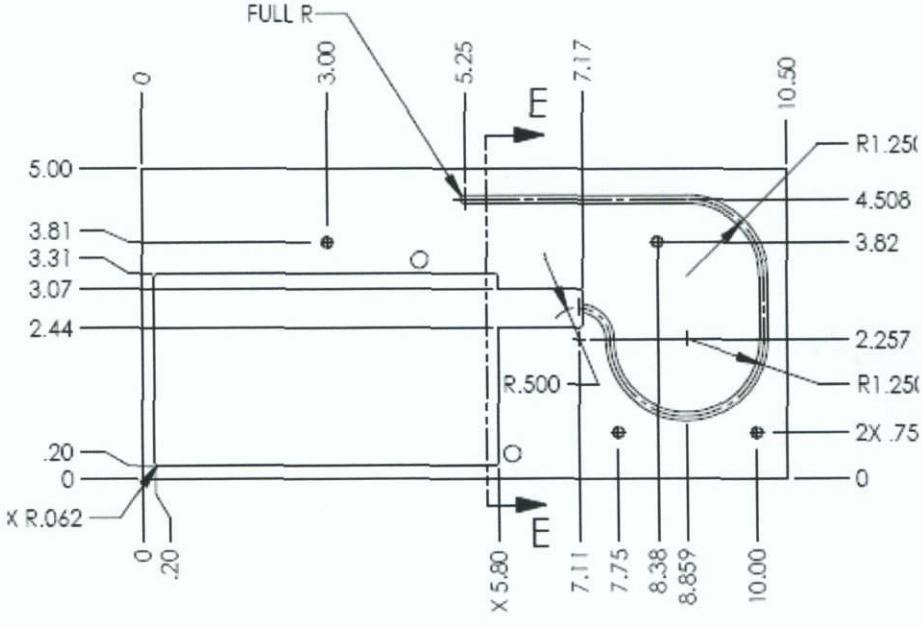


Figure A17-4 Detailed Aortic Arch Fixture



Testing was conducted to compare the particulate test results, baseline and aged, that were obtained using the test fixture shown in **Figure A17-2**, with the particulate test results using the aortic arch test fixture shown in **Figure A17-3**. With the exception of the 50µ test groups, there was no statistical difference demonstrated between the use of the 2 fixture set-ups as show in the analysis below. In the 50µ analysis, the significant difference is attributed to lower particulate in the aortic arch test group. This analysis

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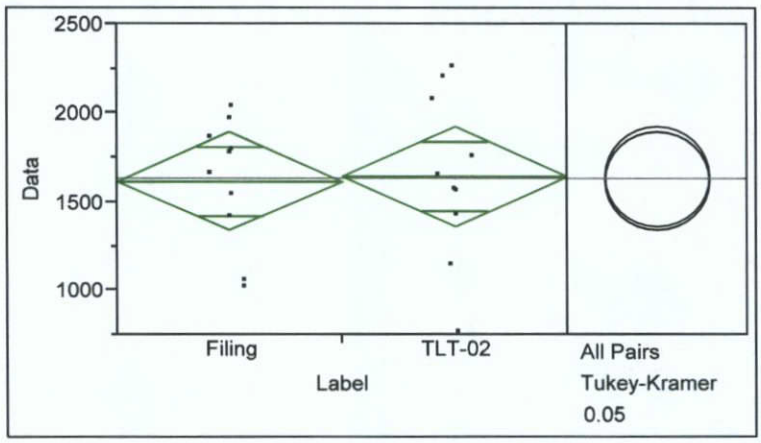
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suggests that the data obtained using the original set-up is representative of data collected while using an aortic arch. **Table A17-3** shows a summary of the data, followed by the statistical analysis show in **Figure A17-5** (10μ), **Figure A17-6** (25μ), **Figure A17-7** (50μ), and **Figure 17-8** (70μ).

(b)(4)

[redacted]

Figure A17-5 Oneway Analysis of Data By Label Bin = 10μ



Means Comparisons for each pair using Tukey-Kramer HSD

(b)(4)

[redacted]

t = 2.10092 alpha = 0.05

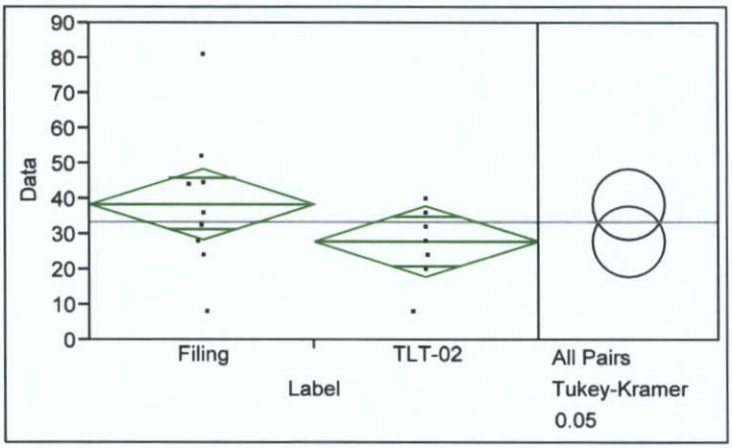
Positive values show pairs of means that are significantly different.

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Figure A17-6 Oneway Analysis of Data By Label Bin = 25µ



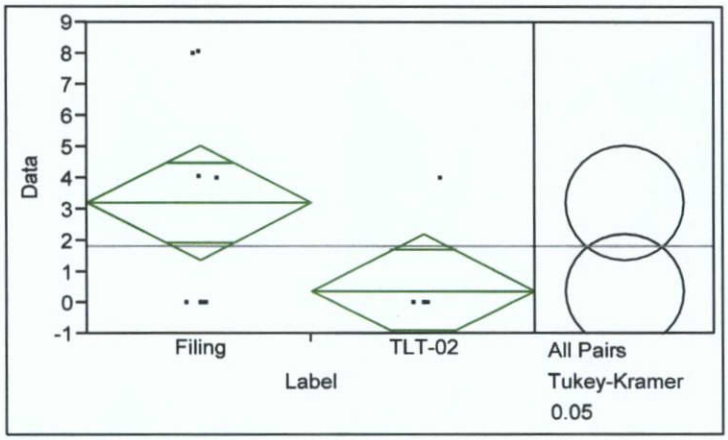
Means Comparisons for each pair using Tukey-Kramer HSD

(b)(4) [redacted]

t = 2.10092 alpha = 0.05

Positive values show pairs of means that are significantly different.

Figure A17-7 Oneway Analysis of Data By Label Bin = 50µ



Means Comparisons for each pair using Tukey-Kramer HSD

(b)(4) [redacted]

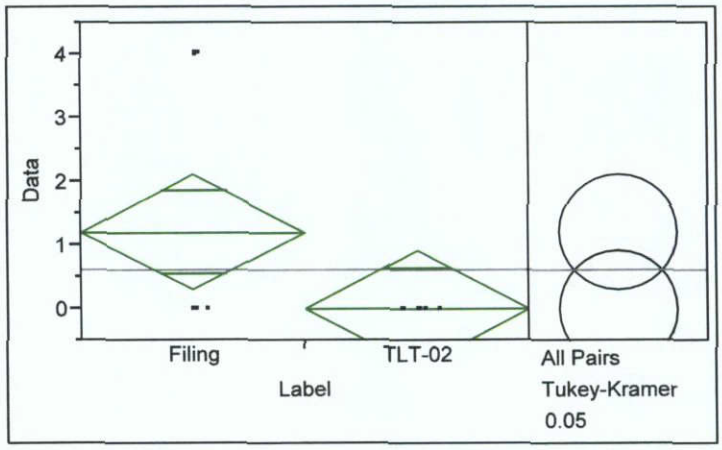
t = 2.10092 alpha = 0.05

Positive values show pairs of means that are significantly different.

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Figure A17-8 Oneway Analysis of Data By Label Bin = 70µ



Means Comparisons for each pair using Tukey-Kramer HSD

(b)(4)

t = 2.10092 alpha = 0.05

Positive values show pairs of means that are significantly different.

Abbott Vascular acknowledges the FDA request to use a tortuous path consistent with that shown in ASTM 2394 Figure X2.4 for the simulated vasculature used for particulate testing. Critical dimensions of the AV test fixture (radius of curvature, diameter of track, etc.) are provided below and equivalence of the AV fixture to the ASTM 2394 Figure X2.4 is discussed below.

For the baseline and aging testing, the 2.00mm, 4.00mm and 5.00mm balloon diameters were tested using the tortuous anatomy fixtures shown in **Figures A17-9, A17-10 and A17-11**. Abbott Vascular considers these fixtures to be appropriate as they mimic *in vivo* physiologic and anatomic worst-case conditions (e.g. tortuous path, ≤15 mm bends, aqueous environment).

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Figure A17-9 Detailed Tortuosity Fixture for 2.00 mm Balloon Diameter



Figure A17-10 Detailed Tortuosity Fixture for 4.00 mm Balloon Diameter



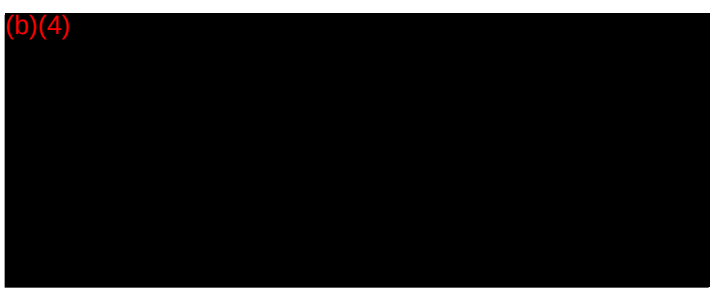
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Figure A17-11 Detailed Tortuosity Fixture for 5.00 mm Balloon Diameter



The inner diameters of the tubing used in the tortuousity fixtures are shown in **Table A17-4**. The tubing inner diameters are larger than the labeled balloon size as they were chosen to ensure that the balloon is inflated to the largest labeled diameter during testing.



The Abbott Vascular simulated vasculature fixtures are robust and suitable for particulate testing due their similarities to ASTM 2394 Fixture X2.4. **Table A17-5** provides a comparison of the current Abbott Vascular simulated vasculature fixtures to ASTM 2394 Figure X2.4. The upper path of Figure X2.4 from ASTM 2394, shown in **Figure A17-12**, was chosen for comparison as it is considered the most challenging of the tracking paths. Abbott Vascular considers the start and end of the highlighted path in **Figure A17-12** to be the ostium and deployment zone respectively.

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Figure A17-12 ASTM 2394 Figure X2.4 with Reference Tracking Path Highlighted

(b)(4)



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Table A17-5 Overview Comparison of Abbott Vascular Current Fixture and ASTM 2394 Figure X2.4 Reference Path shown in Figure A17-12

(b)(4)



Table A17-6 and **Table A17-7** provide the calculations for the arc length summation calculation shown in the first row of Table A17-4. The turn identification numbers are shown in **Figure A17-9**, **Figure A17-10**, and **Figure A17-11** for Abbott Vascular's test fixture and **Figure A17-12** for the ASTM recommended test fixture. The arc lengths were calculated using the following formula:

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Arc Length (s) = Radius (r) * angle (Θ)

For the estimated arc length calculations shown in Table A17-5 and Table A17-6, the angle was converted from degrees to radians using the following formula:

Θ (radians) = Θ (degrees) * 2π (radians)/360 (degrees)

Table A17-6 Arc Length Calculations – ASTM 2394 Figure X2.4

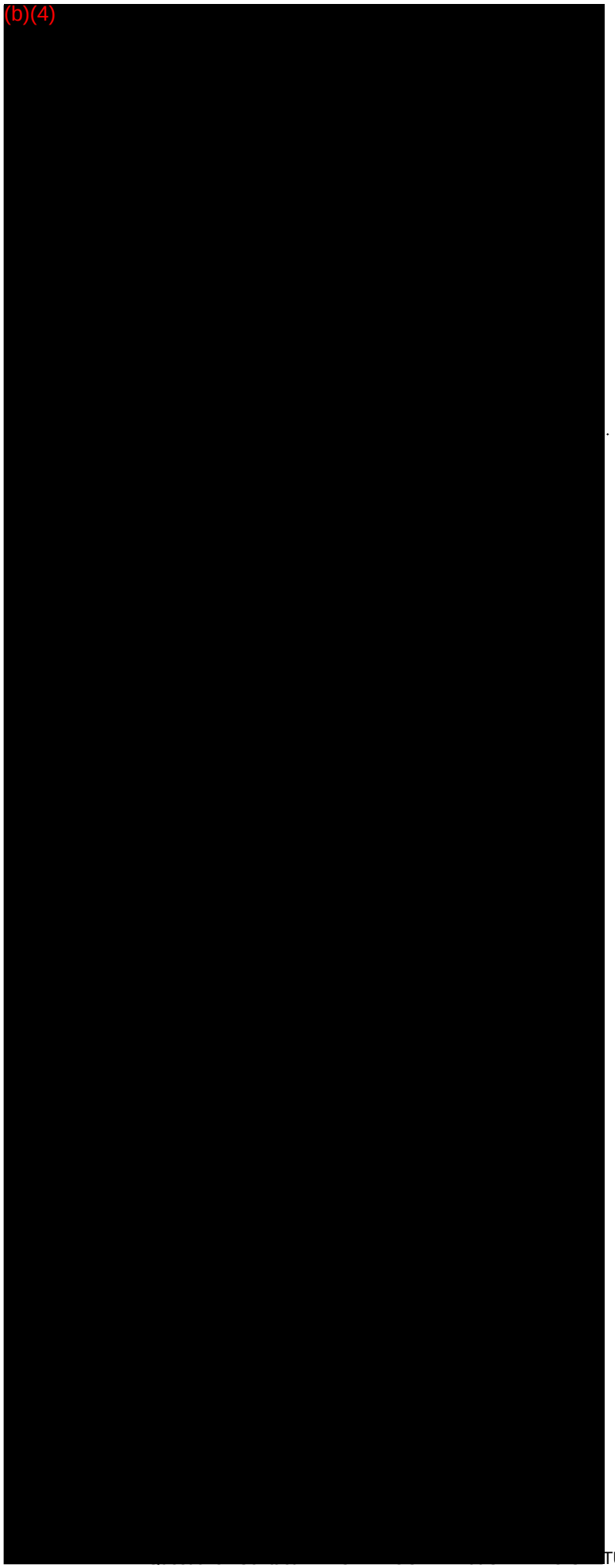
(b)(4)

[redacted]

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A17-13

TUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

c. **You state that "particulate test results are independent of balloon size due to commonality of materials and construction" as a justification for not testing all 4 corner sizes. We do not agree with this statement since the inflation/deflation of the balloon of different sizes will cause different stress/strains in the coating, and it is unclear which sizes may be worst case in this regard. Since your other catheters using the same coating have different balloon materials for the balloon size ranges covered in the TREK and MINI TREK, we cannot conclude that the particulation behavior will be the same. Please include 4 corner sizes for your repeated testing. For aged sample testing, please include the device size that was worst case for each chassis size.**

(b)(4)

[redacted]

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d. We recommend that the total number of particulates be reported in each of three size ranges: ≥ 10µm, ≥ 25µm, and at the largest size for which validation yields ≥ 75% recovery. At a minimum, the largest size should be ≥ 50µm. Your testing did not include the largest particle size bin.

(b)(4)

[redacted]

Table A17-8 Catheter Coating Particulates - Baseline

(b)(4)

[redacted]

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Table A17-9 Catheter Coating Particulates – Aged 2 Years

(b)(4)



e. **Please perform a validation test for your test fixture (spike and recovery test using particles of known size and quantity, for each size bin outlined in part d above), and provide a complete test report for this validation. FDA is amenable to reviewing your test protocol informally prior to test initiation.**

(b)(4)



f. **Please clarify what accessory devices (guide catheter and guide wire) and stents were used in your test.**

(b)(4)



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g. **In your IFU p. 6 you state "After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile, heparinized normal saline and stored. Prior to reinsertion, the balloon should be submerged in sterile, heparinized normal saline to reactivate the coating." However, this process of wiping with gauze and reinserting was not performed for your particulates test. Please include these steps in your new particulates testing.**

(b)(4) [redacted]

h. **You have performed 3 inflations in the overlapped stents in your fixture. The maximum number of inflations was not specified in your instructions for use (IFU). Please perform the same number of maximum inflations in your particulate test, to the maximum labeled diameter, as you intend to state in your IFU, and update your IFU accordingly.**

Abbott Vascular has revised the IFU to include the maximum number of inflations (10

(b)(4) [redacted]

(b)(4) [redacted]

A17-17

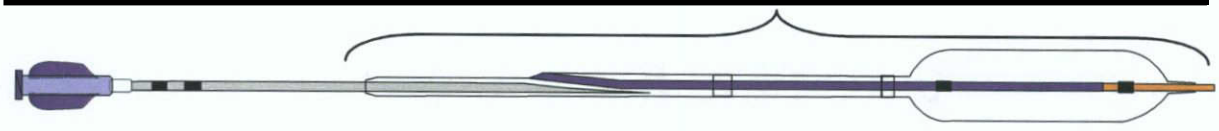
508

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i. **Please perform a visual assessment of your catheter coating integrity after particulates testing. We recommend that you appropriately quantify characteristics such as continuity and voids in the coating, using a sufficient magnification to visualize defects. Please also include representative images (including worst-case) in your test report.**

(b)(4)



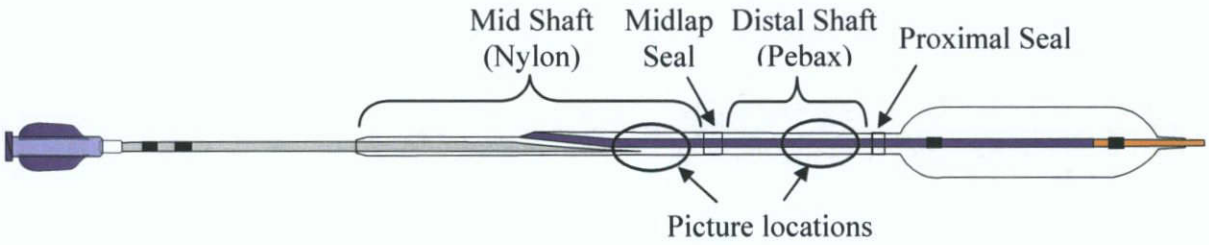
(b)(4)

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(b)(4)

Figure A17-14 Catheter Image Locations



(b)(4)

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Figure A17-15 Hydrophilic Coated Units, Red Dye, Pre-Particulate Test, 3 cm from Midlap Seal

(b)(4)



(b)(4)

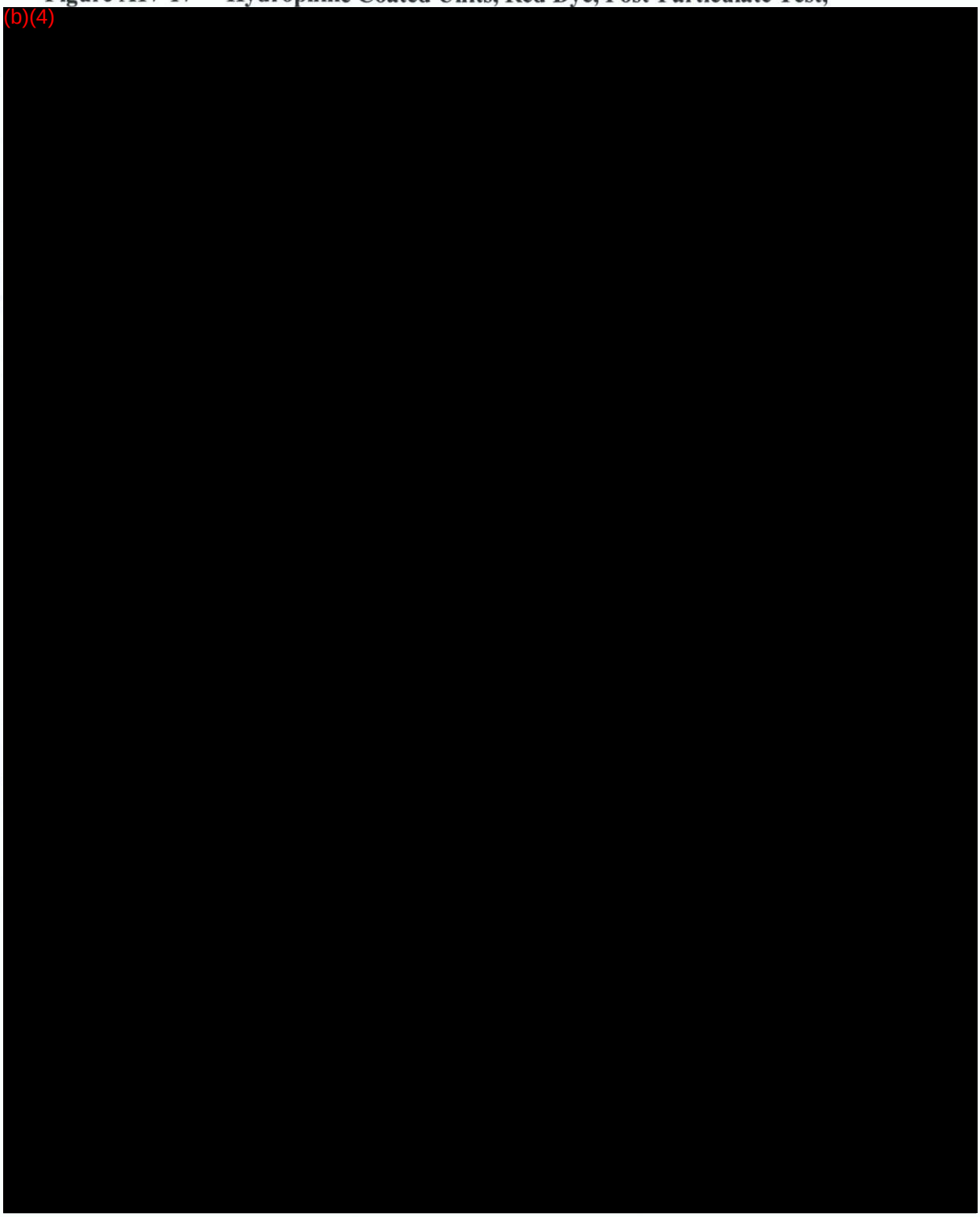


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Figure A17-17 Hydrophilic Coated Units, Red Dye, Post-Particulate Test,

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Abbott Vascular

Test Method Parameter Study Report
Particulates: Track, Inflate on a Bend
STM2066783, STM2071031, STM2072323
Precision

July 19, 2010

(b) (6)

[redacted]

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1. Purpose

This document is a supplement to revisions A and B of this report (RPT2070463).

In the previous two studies, acceptance criteria were as follows:

- Minimum 90 percent for 10 and 25 micron spheres
- Minimum 75 percent for 50 and 70 micron spheres

In this study, maximum recovery limits were added:

- 90 ≤ percent recovery ≤ 110 for 10 and 25 micron spheres
- 75 ≤ percent recovery ≤ 110 for 50 and 70 micron spheres

2. Scope

The results of this study apply to any test method using the same HIAC instrument and test fixtures within the range utilized in this protocol, and using equivalent test parameters.

3. Definitions

For the purpose of this protocol, the following terms and definitions apply

Cleanliness Limit	- USP<788> guidance for no more than 25 particles 10 microns and larger in a 25 mL volume tested as an acceptable background count
HIAC Royco	- brand name of a laser obscuration particle counter
Particle-free water	- water that meets cleanliness limit
PS	- Product Specification (document prefix)
RHV	- Rotating Hemostatic Valve
STM	- Standard Test Method (document prefix)
USP	- United States Pharmacopocia

4. References

ISO 21501-3	Determination of particle size distribution – Single particle light interaction methods – Part 3: Light extinction liquid-borne particle counter
RPT2070463-P Rev C	Test Method Parameter Study Protocol. Particulates: Track, Inflate on a Bend. STM2066783, STM2071031, STM2072323. Precision
STM2066783 Rev C	Particulates: Track and Inflate on a Bend
STM2071031 Rev D	Particulates: Stent on a Bend
STM2072323 Rev 4	Particulate: BVS Tracking Test
TLT2075246	Embolic Preconditioning Bracket (Reference Protocol Attachment, currently being archived in ViewPoint)
TLT2075247-XX	Embolic Preconditioning Fixture (Reference Protocol Attachment, currently being archived in ViewPoint)
USP 32 <788>	Particulate Matter in Injections

5. Experimental Overview

As described in the protocol (RPT2070463-P Rev C), instead of assuming that the solution delivered from the pipettors contained the labeled nominal concentration of the Duke Scientific COUNT-CAL product (3,000 spheres/mL), the HIAC was used to count and inject the spheres into the most proximal end of the test system (the proximal end of the guiding catheter).

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Two other items were investigated in this study:

- the use of a Teflon-jacketed instead of glass-jacketed stir bar
- the precision of a 15 mL retest of the same solution after a cleanliness check of the HIAC and an additional degas procedure.

Three different fixtures were used by three different operators on two different HIAC sensors.

Because this test strategy no longer directly evaluates the capabilities of the HIAC instrument, each of the two sensors used was first verified to have acceptable count and size accuracy by following the procedures described in ISO21501-3.

The equipment and materials used in this study are listed in Attachment A.

6. Deviations

In one of the retest procedures, a 50 mL sample was mistakenly used instead of the 15 mL set by the protocol. This is acceptable because the estimate of the total particulate matter in the container should not be sensitive to sampled volume in that range. The retest sample that used a 50 mL sample passed the recovery acceptance criteria.

7. Data Analysis/Results

Sensor Verification

For the ISO HIAC sensor verification, both sensors were observed to meet the acceptance criteria described in the ISO. The count accuracy was within the ISO limit of 100 ± 20% ; the size accuracy was within the ISO limit ± 10%. (Reference Attachment B.)

Recovery Studies

The summary recovery results are shown in the next three tables.

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8. Conclusions

Retest Procedure – an investigation tool during troubleshooting

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Attachment A: Equipment and Materials

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ATTACHMENT 18

Question 18:

It appears that you have used a room temperature value of 20°C (68°F) to calculate your accelerated aging factor, which is less conservative than using a more typical value for room temperature (23-25°C). FDA believes that the devices will be exposed to ambient temperatures above 20°C during transport and storage. If a room temperature value of 25°C was used, 65 days of aging at 55°C (functional testing) and 46 days of aging at 60°C (packaging) would be equivalent to 520 days, rather than 2 years as you have calculated. Please either reduce your shelf life claim in the future marketing application to match the shelf life duration supported with testing using a more conservative value for room temperature, perform additional shelf life testing to support your proposed 6 month shelf life, or provide a scientific justification for why you believe a room temperature value of 20°C is appropriate.

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ACCELERATED AGING TEST PROTOCOL

Purpose

The purpose of this protocol is to outline and document the accelerated aging conditions and functional testing necessary to evaluate any degradation in the materials of the TREK RX and MINI TREK RX Coronary Dilatation Catheters over a three (3) year shelf life.

The aging testing will demonstrate the following:

- The product conforms with the labeled product shelf life by meeting its functional and performance specifications after exposure to aging conditions.
- The product packaging adequately protects the device during simulated handling and storage.

The device will function as intended after exposure to extreme temperature conditions for relatively short periods of time, as might occur during normal transportation processes.

Materials

- EtO Sterilized (one time) TREK RX and MINI TREK RX Coronary Dilatation Catheters
- Environmental Chamber
- Other materials as listed under each test performed

Discussion

(b)(4)



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ACCELERATED AGING TEST PROTOCOL - *Continued*

(b)(4)

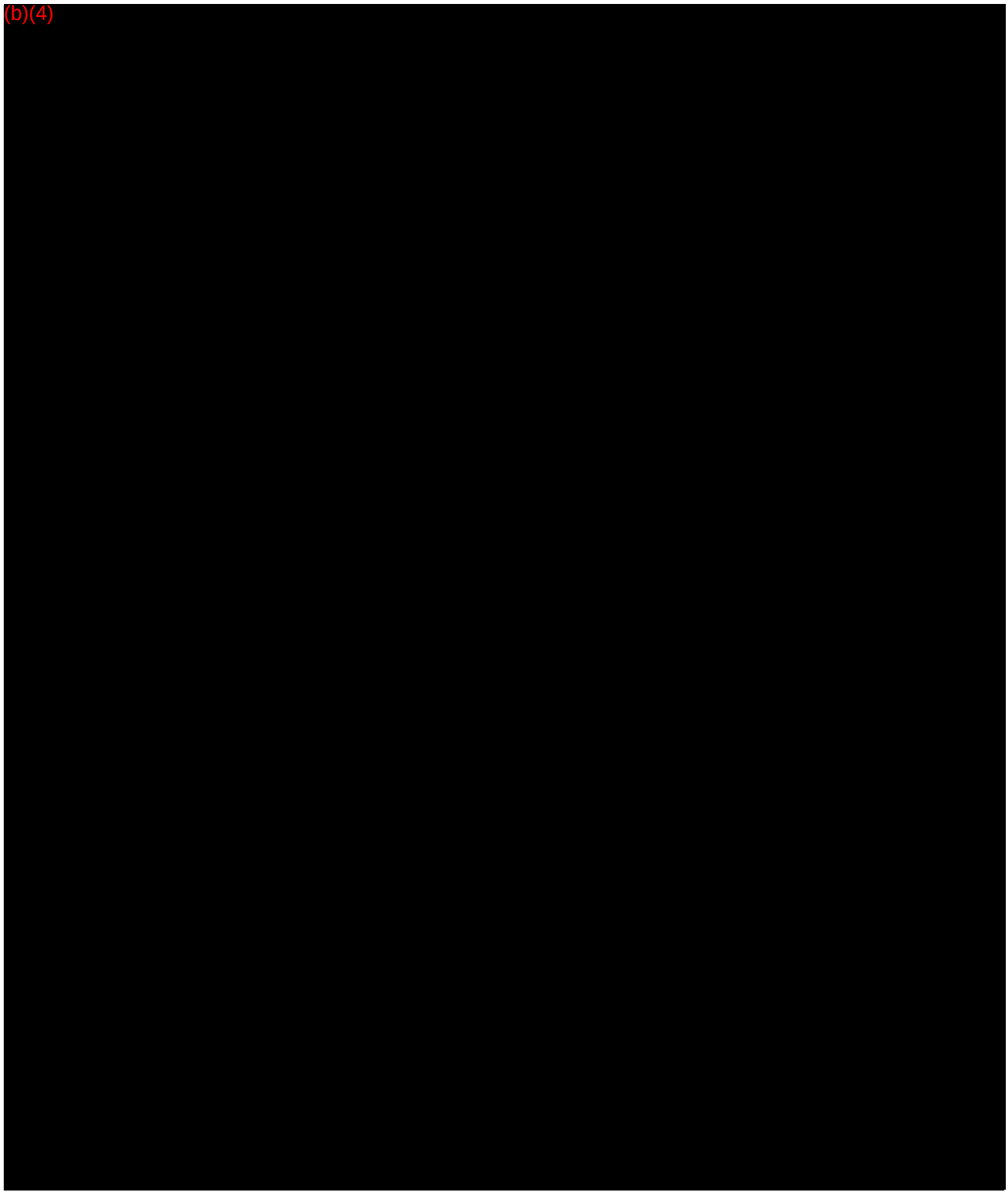


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ACCELERATED AGING TEST PROTOCOL - *Continued*

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ACCELERATED AGING TEST PROTOCOL - *Continued*

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ATTACHMENT 19

Question 19:

Please address the following concerns regarding your Instructions for Use (IFU):

a. **Please include the maximum number of inflation cycles, both in a stent (post dilatation) and not in a stent**

(b)(4) [redacted]

b. **The Rx only symbol was not included in the graphical symbols glossary at the end of your IFU. Please add the symbol to your glossary. Please also add the statement "Caution: Federal law restricts this device to sale by or on the order of a physician."**

(b)(4) [redacted]

c. ***Please provide a red-lined copy of your IFU with the above changes incorporated.***

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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TREK OTW and MINI TREK OTW Coronary Dilatation Catheter

℞ ONLY

CE 0086

CAUTION

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DESCRIPTION

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is a two-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon with contrast medium. The second lumen permits the use of a guide wire to facilitate advancement of the dilatation catheter to and through the stenosis to be dilated, and the injection of contrast and / or medication through the distal tip. The dilatation catheter is coated with HYDROCOAT hydrophilic coating that is activated when wet.

This device has several markers. The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure. The proximal shaft has proximal markers that aid in gauging dilatation catheter position relative to the guiding catheter tip (marker located closest to the dilatation catheter adapter is for femoral guiding catheters and the other marker is for brachial guiding catheters).

The two-arm adapter on the proximal end of the dilatation catheter provides access to the inflation lumen and the guide wire lumen. The side arm connects with the inflation lumen and has a Luer-lock fitting for connecting the dilatation catheter to an inflation device. The central arm connects with the guide wire lumen, which allows for free movement of the inserted guide wire.

HOW SUPPLIED

Sterile – This device is sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is *open or damaged*.

This single use device cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and / or chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to contamination due to narrow gaps and / or spaces and diminished safety and / or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) TREK OTW or MINI TREK OTW Coronary Dilatation Catheter, one (1) protective sheath, and one (1) compliance card

Storage – Store in a dry, dark, cool place.

INDICATIONS

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is indicated for:

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- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion
- Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction
- *Balloon dilatation of a stent after implantation* (balloon models 2.00 mm – 5.00 mm only)

CONTRAINDICATIONS

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is not intended to be used to treat patients with:

- An unprotected left main coronary artery
- A coronary artery spasm in the absence of a significant stenosis

WARNINGS

This device is intended for one time use only. DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent overpressurization.

To reduce the potential for vessel damage, *the inflated diameter of the balloon should approximate the* diameter of the vessel just proximal and distal to the stenosis.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of resistance before proceeding.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked; this may result in the shaft breaking. Instead, prepare a new catheter.

Do not torque the catheter more than one (1) full turn.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60 – 85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.

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In the event of catheter damage / separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

PRECAUTIONS

Note the "Use by" date specified on the package.

Inspect all product prior to use. Do not use if the package is open or damaged.

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time as determined by the physician after the procedure.

If the surface of the TREK OTW or MINI TREK OTW Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the TREK OTW or MINI TREK OTW Coronary Dilatation Catheter into the coil dispenser after procedural use.

This device should be used only by physicians experienced in angiography and PTCA and / or percutaneous transluminal angioplasty.

ADVERSE EVENTS

Possible adverse effects include, but are not limited to, the following:

- Acute myocardial infarction
- Arrhythmias, including ventricular fibrillation
- *Arteriovenous fistula*
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture or injury
- Death
- Drug reactions, allergic reaction to contrast medium
- Embolism
- Hemorrhage or hematoma
- Hypo / hypertension
- Infection
- Restenosis of the dilated vessel
- Total occlusion of the coronary artery or bypass graft
- Unstable angina

CLINICAL AND LABORATORY RESULTS

To evaluate the safety and effectiveness of direct PTCA as a treatment for patients with ST-segment elevation acute myocardial infarction, ACS conducted a multicenter, prospective, randomized clinical trial using primarily ACS coronary dilatation catheters. The GUSTO II Direct PTCA Substudy (GUSTO IIb) evaluated treatment of patients presenting within 12 hours of ST-segment elevation myocardial infarction with direct PTCA or accelerated recombinant tissue plasminogen activator (t-PA). The primary hypothesis was that for patients with suspected acute myocardial infarction, with ST-segment elevation, direct PTCA would result in a lower rate of 30-day mortality, nonfatal reinfarction, and nonfatal disabling stroke when compared with thrombolytic therapy.

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A total of 1138 patients were enrolled in this trial at 60 centers in 9 countries from North America, Europe, and Australia over a period of 17 months. Investigator selection criteria included those physicians who had significant experience performing primary angioplasty for patients with acute myocardial infarctions, who fulfilled the 1993 ACC volume criteria of at least 50 to 75 cases of angioplasty per year. Investigational institutions were required to have performed at least 200 angioplasties per year and have a 24-hour on call team with an established system for operating room back-up. Five hundred sixty-five patients were assigned to primary angioplasty and 573 to accelerated recombinant tissue plasminogen activator (t-PA). At initial enrollment, the first 1012 patients were also randomized in a factorial design, to intravenous heparin or intravenous hirudin, as part of the GUSTO II trial. Thereafter, all patients received intravenous heparin. At enrollment, patients were given chewable aspirin (160 mg was recommended) followed by a daily dose of 80 to 325 mg. Patients received standard medical care post assigned treatment. Other testing and adjunctive therapies were left up to the discretion of the physician.

Of the patients randomized to t-PA, 94.6% (542/573) received t-PA, 1.6% (9/573) received streptokinase, and 1.7% (10/573) had direct angioplasty. Eighty two patients (14.4%) required emergency angiography and sixty (10.5%) required emergency PTCA. Two hundred seventy (47.3%) had elective angiography and 61 (10.7%) had elective PTCA. The in-hospital procedural characteristics for patients randomized to PTCA, were 73.3% (374/510) of the infarct arteries occluded (TIMI grade 0 or 1 flow) at initial catheterization (core lab) and 79.2% (446/563) patients received PTCA. Patency after angioplasty (TIMI grade 2 or 3 flow) was achieved in 93.1% (473/508) of patients (core lab). Twenty-two (4%) required emergency angiography and 19 (3.5%) required emergency PTCA. Nineteen (3.5%) had elective angiography, and 5 (0.9%) had elective PTCA. The mean time from arrival at the hospital to treatment for patients randomized to accelerated t-PA was 1.2 ± 0.9 hours and for the PTCA treatment group was 2.2 ± 0.9 hours.

When comparing the treatment of patients with ST-segment elevation myocardial infarction with direct PTCA to treatment with accelerated t-PA, PTCA resulted in a statistically significant lower 30-day composite endpoint rate of death, reinfarction, and nonfatal disabling stroke of 9.6% versus 13.7%, respectively, (odds ratio = 0.67, p = 0.033). Additionally, the direct PTCA group had a statistically significant lower rate of recurrent ischemia at 30 days when compared to the t-PA group 5.5% (29/526) versus 9.0% (48/532), respectively, (odds ratio = 0.59, p = 0.03). The overall stroke rate for this study was 1.6% (18/1133). The stroke rate for patients treated with direct PTCA was 1.3% (7/562) versus 1.9% (11/571) for patients treated with t-PA (odds ratio = 0.64, p value = 0.36). The accelerated t-PA treatment group had a statistically significant higher rate of intracranial hemorrhagic strokes, when compared to PTCA: 1.5% (8/571) versus 0%, respectively (odds ratio = 0.06, p = 0.005). There was a statistically significant higher overall rate of bleeding in the PTCA group versus the t-PA group: 40.3% (227/563) versus 34.2% (195/571) (odds ratio = 1.30, p = 0.03). The rate of severe or life-threatening bleeding was equivalent in both treatment groups. Seventy percent (161/227) of bleeding complications in the PTCA treatment group were related to vascular access, and 62.9% (142/227) were mild in nature.

At 180 days, there was no statistical difference in the composite rate of death, reinfarction, and nonfatal disabling stroke for accelerated t-PA versus direct PTCA, 16.8% (87/517) versus 14.7% (75/509), respectively, (odds ratio = 0.88, p = 0.36). The overall rate of re-admission to the hospital for chest pain, myocardial infarction, stroke, and repeat cardiac procedures was similar between the two groups. At one year there is no statistical difference in the rate of death for accelerated t-PA versus PTCA 10.3% (52/507) versus 9.2% (46/500), respectively (odds ratio = 0.89, p = 0.57).

Direct PTCA with ACS coronary dilatation catheters is safe and effective in eligible patients presenting within 12 hours of ST-segment elevation myocardial infarction, providing a reduced composite event rate at 30 days with an equivalent clinical outcome at 180 days and one year compared with accelerated t-PA.

Direct angioplasty, when it can be accomplished on a prompt basis by experienced physicians at centers with catheterization laboratory availability, should be considered a primary treatment option for patients with acute myocardial infarction.

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MATERIALS REQUIRED

Single Use, Sterile Items (Do not resterilize or reuse.)

- Sterile heparinized normal saline
- Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery
- Hemostatic valve(s)
- Contrast medium diluted 1:1 with normal saline
- 20 cc Luer-lock syringe (optional)
- Appropriately-sized guide wire
  (diameter not to exceed the maximum guide wire for the dilatation catheter; see product label)
- *Guide wire introducer*
- Guide wire torque device
- Inflation device

PREPARATION FOR USE

Inspect all product prior to use. Examine the dilatation catheter for bends, kinks, or other damage. Do not use if the package is open or damaged, or if the product is damaged.

Prepare equipment to be used following manufacturer's instructions or standard procedure.

Complete the following steps to prepare the TREK OTW or MINI TREK OTW Coronary Dilatation Catheter for use:

1. Remove the protective mandrel from the distal tip of the dilatation catheter.
2. Slide the protective sheath off the balloon.

   Note: Submerge the balloon in sterile heparinized normal saline during balloon preparation to activate the coating.
3. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.
4. Evacuate air from the balloon segment using the following procedure:

   a. Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommended contrast medium.

   b. After attaching the syringe or inflation device to the balloon inflation lumen, orient the catheter with the distal tip and the balloon pointing in a downward vertical position.

   c. Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.

   d. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.

   e. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.

   f. Slowly release the device pressure to neutral.

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g. Disconnect the 20 cc syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without introducing air into the system.

CAUTION: All air must be removed from the balloon and displaced with contrast medium (diluted 1:1 with normal saline) prior to inserting into the body (repeat steps 4a through 4g, if necessary); otherwise, complications may occur.

INSTRUCTIONS FOR USE

1. Flush and fill the guide wire lumen of the dilatation catheter with heparinized normal saline.

2. Insert a guide wire carefully into and through the lumen of the dilatation catheter via the guide wire port of the two-arm adapter using a guide wire introducer, if desired. When complete, withdraw the guide wire introducer, if used.

3. Open the hemostatic valve. Insert the dilatation catheter and guide wire assembly through the hemostatic valve into the guiding catheter. To facilitate insertion, the balloon must be fully deflated to *negative pressure*.

   Note: Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the catheter.

4. Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibiting movement of the dilatation catheter. This will allow continuous recording of the proximal coronary artery pressure.

   Note: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the *balloon or restricts guide* wire movement.

5. Advance the dilatation catheter and guide wire until the appropriate proximal marker aligns with the hemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.

6. Attach a torque device for the guide wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

   Note: The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is designed to allow the exchange of guide wires while maintaining position of the dilatation catheter in the coronary artery.

7. Advance the dilatation catheter over the guide wire and into the stenosis (or stent for *post-implant* dilatation). Inflate the balloon to a very low pressure (1 atm or 1 bar or 15 psi) to confirm that the balloon is correctly positioned.

   Note: When using the dual wire technique, a dual hemostatic valve should be used and care taken when introducing, torquing, and removing one or both wires to avoid entanglement. Guide wires should not be rotated more than 180 degrees in either direction during the dual wire procedure. It is recommended that one wire be completely withdrawn from the patient before removing additional equipment.

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8. Inflate the balloon (not to exceed 10 total inflations in a stent or 20 total inflations without a stent) to perform PTCA (or post-implant dilatation) per standard procedure. Maintain negative pressure on the balloon between inflations.

9. Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the hemostatic valve. Tighten the hemostatic valve.

   Note: After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile heparinized normal saline and stored, submerged in a basin of sterile heparinized normal saline. Prior to reinsertion, the balloon should be submerged in sterile heparinized normal saline to reactivate the coating.

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by the American College of Cardiology and the American Heart Association.

PATENTS AND TRADEMARKS

This product and / or its use are covered by one or more of the following United States Patents: 5,046,503; 5,137,513; 5,159,937; 5,176,661; 5,234,002; 5,242,396; 5,256,143; 5,290,230; 5,300,025; 5,316,706; 5,318,527; 5,324,259; 5,344,426; 5,346,505; 5,397,305; 5,411,476; 5,480,383; 5,496,275; 5,496,346; 5,498,240; 5,507,301; 5,516,336; 5,525,388; 5,533,968; 5,542,925; 5,554,120; 5,554,121; 5,565,523; 5,573,508; 5,632,754; 5,693,015; 5,743,875; 5,747,591; 5,816,923; 5,849,846; 5,868,706; 5,868,767; 5,902,290; 5,993,460; 6,013,069; 6,013,728; 6,027,475; 6,036,707; 6,059,770; 6,061,588; 6,129,707; 6,136,011; 6,139,525; 6,165,152; 6,179,810; 6,206,852; 6,217,547; 6,221,425; 6,224,803; 6,238,376; 6,248,092; 6,251,094; 6,368,301; 6,488,688; 6,572,813; 6,579,484; 6,663,614; 7,273,487. Other U.S. patents pending. Foreign patents issued and pending.

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Graphical Symbols for Medical Device Labeling

Manufacturer	REF Catalogue number	F French size
Do not resterilize	STERILE EO Sterilized using ethylene oxide	Consult instructions for use
Use by	LOT Batch code	Do not reuse
Date of manufacture	Outer diameter	
Contents (numeral represents quantity of units inside)		

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ATTACHMENT 20

This attachment includes information amending P810046/S235 to add the over-the-wire platform, TREK OTW and MINI TREK OTW, to the previously submitted TREK RX and MINI TREK RX.

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SECTION 3 - SUMMARY OF STUDIES

3.1 INDICATIONS FOR USE

The indications and contraindications for the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are in accordance with the previously approved PMA Supplement for the VOYAGER® OTW Coronary Dilatation Catheter (P810046/S214, approved March 2, 2004) and are identical to those of the TREK RX and MINI TREK Coronary Dilatation Catheters currently under review in this PMA Supplement (P810046/S235, submitted March 19, 2010).

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are indicated for: (a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion; (b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction; (c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

3.2 DEVICE DESCRIPTION

The device generic and trade names are as follows:

Device Generic Name:	Coronary Balloon Dilatation Catheter
Device Trade Name:	TREK™ OTW Coronary Dilatation Catheter MINI TREK™ OTW Coronary Dilatation Catheter

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are similar in design, materials, and indications to the currently approved VOYAGER® OTW Coronary Dilatation Catheter (P810046/S214, approved March 12, 2004). Additionally, the distal portion of the catheter from the mid-lap joint to the tip, including all balloon diameters and lengths, is identical to the same distal portion of the TREK RX and MINI TREK RX Coronary Dilatation Catheters.

The design of the TREK OTW and MINI TREK OTW catheters, along with the TREK RX and MINI TREK RX submitted earlier as part of PMA Supplement P810046/S2325, includes the following:

- A Pebax balloon with a Rated Burst Pressure (RBP) of 14 atm. Pebax 70D is used for the 1.5 mm through 2.00 mm balloons. A co-extrusion of Pebax 70D over Pebax 63D is used for the 2.50 mm through 5.0 mm balloons.

- A tip-through design where the soft tip is directly joined to the inner member under the balloon's distal taper.

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Table 3-1 provides the size matrix for the MINI TREK OTW and the TREK OTW which is identical to the MINI TREK RX and TREK RX submitted earlier as part of P810046/S235.

Table 3-1 Size Matrix

Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK OTW Coronary Dilatation Catheter							
1.50	X	X	X	X	X		
2.00	X	X	X	X	X	X	X
TREK OTW Coronary Dilatation Catheter							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50			X	X			
5.00			X	X			

Table 3-2 on the following pages provides the product labeling specifications for the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters. Balloon diameters and lengths, RBP, catheter length, maximum guide wire outer diameter, and number of balloon markers is identical to the TREK RX and MINI TREK RX submitted earlier in PMA Supplement P810046/S235.

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3.3 ALTERNATE PRACTICES AND PROCEDURES

Patients with coronary artery disease receive exercise, diet and drug therapy. If the disease progresses, percutaneous transluminal coronary angioplasty (PTCA), stenting or coronary bypass graft surgery may be performed to relieve the anginal syndrome. PTCA may be performed with a currently marketed coronary balloon dilatation catheter.

3.4 MARKETING HISTORY

The TREK OTW and MINI TREK OTW catheters have not been approved for marketing in the United States or any other country.

3.5 SUMMARY OF STUDIES

To evaluate the safety and efficacy of the TREK OTW and MINI TREK OTW catheters, *in vitro* and *in vivo* laboratory tests were conducted as follows:

3.5.1 Biocompatibility Tests

The TREK OTW and MINI TREK OTW were subjected to biocompatibility testing in accordance with ISO 10993-1:2003, *Biological evaluation of medical devices – Part 1: Evaluation and testing*, and *Draft Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* May 30, 2008. These devices were found to be acceptable for clinical use. The biocompatibility testing was conducted in accordance with the Federal Good Laboratory Practices Regulations (21 CFR §58 and 40 C R §160).

The catheter chassis materials and manufacturing process are identical for all balloon sizes, however, two balloon materials are used. The balloon material for the 2.00 mm through 5.00 mm balloon diameters, TREK OTW, is comprised of a co-extrusion of Pebax 70D over Pebax 63D, which remain as two distinct layers in the balloon. The balloon material for the 1.50 mm through 2.00 mm balloon diameters is comprised of Pebax 70D. The design and manufacturing processes for the distal portion of the catheter from the mid-lap seal to the tip are identical to MINI TREK RX and TREK RX. Biocompatibility testing was conducted using device with balloons comprised of both the Pebax 70D and Pebax 63D materials, TREK OTW. The MINI TREK RX without the Pebax 63D in the balloons is otherwise identical in materials and subjected to the identical type of manufacturing processes as the balloons for the TREK RX. Both Pebax 70D and Pebax 63D are present in other extruded materials in the TREK OTW and MINI TREK OTW.

The results of the biocompatibility testing are located in **Attachment 20, Section 6.1**.

3.5.2 Sterility Tests

The TREK OTW and MINI TREK OTW are sterilized by means of exposure to ethylene oxide gas (EtO) using the identical processes and cycles as described in the PMA

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Supplement for the MINI TREK RX and TREK RX. Annual cycle revalidations continue to demonstrate that the cycle to be used for the TREK OTW and MINI TREK OTW, along with other products within its sterilization family achieve an SAL of less than 10^{-6}.

The sterility testing previously conducted and its applicability to the TREK RX and MINI TREK is discussed in **Attachment 20, Section 6.2**.

3.5.3 Packaging Integrity Testing

The MINI TREK OTW and TREK OTW Coronary Dilatation Catheter uses identical packaging as described in the PMA Supplement for the VOYAGER™ RX Coronary Dilatation Catheter (P810046/S216, approved June 18, 2004), and other products within this device family with minor changes as described in **Attachment 20, Section 6.3**. Packaging is identical to that of the MINI TREK RX and TREK RX.

Package integrity testing was conducted in order to demonstrate compliance to ISO 11607-1:2006, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*, and ISO 11607-2:2006, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*. This protocol, designed to support a shelf life of up to three (3) years, has been included in **Attachment 20, Section 6.3**. Completed testing to date supports a shelf life of three (3) years.

3.5.4 *In Vitro* Bench Testing

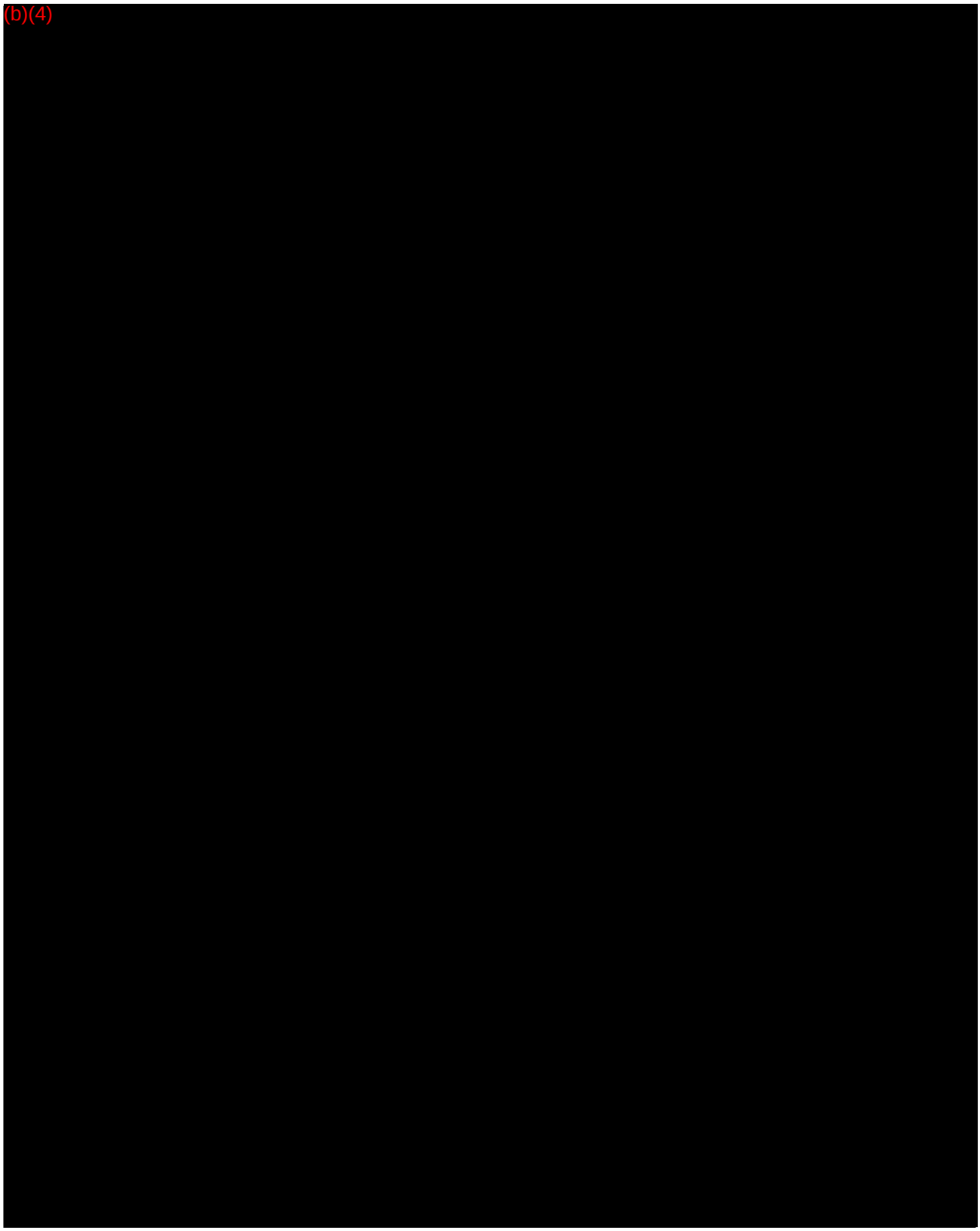
In vitro bench testing was performed to assess the functional characteristics of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheter. The results indicate that the catheters adequately satisfied the relevant FDA reliability guidelines as outlined in *Draft Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* May 30, 2008. In addition, the accelerated aging test results indicate that these catheters will maintain their functional characteristics for their current shelf life of six (6) months. The shelf life may be extended to up to three (3) years, as sufficient accelerated aging data is collected, based on the same test protocol and acceptance criteria. Where device design and manufacturing is identical to the TREK™ RX and MINI TREK™ RX, testing previously preformed and included in P810046/S235 is leveraged and additional testing of the OTW version of the device was not repeated.

The samples were subjected to the *in vitro* bench tests provided in **Table 3-3**.

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3.5.5 Shelf Life

The TREK OTW and MINI TREK OTW were subjected to accelerated aging and evaluated to ensure adherence to the established product specification. The data collected to date ensure a product shelf life of six (6) months.

The shelf life will be extended to three (3) years, as sufficient accelerated aging data is collected, based on the same test protocol and acceptance criteria. Abbott Vascular will also collect corresponding real time aging data, summaries of which will be provided in subsequent periodic reports. Abbott Vascular will notify FDA via a periodic report to P810046 when the shelf life is extended according to the approved protocol included in this PMA Supplement. Summaries of real-time test results according to this protocol will also be provided via periodic report as testing is completed.

3.5.6 *In Vivo* Animal Tests

The TREK OTW and MINI TREK OTW are similar in design and materials to the VOYAGER® OTW (P810046/S214) Coronary Dilatation Catheter. The indications and risks associated with the TREK OTW and MINI TREK OTW are identical to other Abbott Vascular coronary dilatation catheters that are currently marketed under Pre-Market Approval Application P810046. Therefore, *in vivo* animal studies were not deemed to be necessary.

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3.5.7 Clinical Studies

The TREK OTW and MINI TREK OTW are similar to the VOYAGER® OTW (P810046/S214) Coronary Dilatation Catheter and other currently marketed Abbott Vascular coronary dilatation catheters in design, materials, indications for use and risks. Therefore, clinical studies were not deemed to be necessary.

3.6 CONCLUSIONS DRAWN FROM THE STUDIES

The safety and efficacy of the TREK OTW and MINI TREK OTW is based on results obtained from *in vitro* testing. The test results reveal the following:

- The results obtained from the biocompatibility testing indicate that the TREK OTW and MINI TREK OTW are acceptable for short-term use in the cardiovascular system.

- The *in vitro* testing demonstrated that the TREK OTW and MINI TREK OTW meet the relevant requirements set forth in *Draft Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* May 30, 2008.

The information contained within this PMA Supplement provides reasonable assurance that the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are safe and effective during PTCA as described in the product labeling.

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SECTION 4

DEVICE DESCRIPTION AND MANUFACTURING INFORMATION

4.1 DEVICE DESCRIPTION

The TREK OTW and MINI TREK OTW are similar in design, materials and indication to the VOYAGER® OTW Coronary Dilatation Catheter (P810046/S214, approved March 12, 2004, and P810046/S222, approved September 27, 2007). The design and materials of the balloon are similar to the balloon of the VOYAGER® NC Coronary Dilatation Catheter (P810046/S226, approved August 21, 2008). The distal portion of the catheter, from the mid-lap joint to the tip is identical to that of the TREK RX and MINI TREK RX Coronary Dilatation Catheters currently under review (P810046/S235, submitted March 19, 2010).

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are an over-the-wire co-axial design with a balloon at the distal tip. The balloon segment expands to a known diameter and length at a specific inflation pressure and has two radiopaque markers to aid in positioning the balloon in a stenosis. The co-axial shaft consists of a tubular inner and outer member. The central lumen of the inner member permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides annular space for inflation and deflation of the balloon with contrast fluid.

The primary sections of the TREK OTW and MINI TREK OTW, the distal segment and the proximal segment, are described below, followed by design and material comparison tables and drawings.

Distal Segments

Outer Coating

Identical to the TREK RX and MINI TREK RX.

Inner Member

Identical to the TREK RX and MINI TREK RX

Distal Tip

Identical to the TREK RX and MINI TREK RX.

Balloon

Identical to the TREK RX and MINI TREK RX.

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Distal Outer Member

Identical to the TREK RX and MINI TREK RX.

Balloon Markers

Identical to the TREK RX and MINI TREK RX.

Proximal Segments

Proximal Outer Member

The proximal outer member is comprised of one section of variable stiffness, tapered tubing consisting of two material layers, coextruded along the length of the tubing. The inner layer is comprised of nylon and the outer layer is comprised of a polyamide elastomer. The distal end of the proximal outer member is laser bonded to the proximal end of the distal outer member.

Shaft Markers

Two white foil markers are located on the proximal section of the hypotube shaft to indicate when the distal tip of the catheter exits the guiding catheter. The shaft marker is placed 95 cm proximal to the distal tip of the catheter and is for use with brachial guiding catheters. The second shaft marker is placed 105 cm proximal to the distal tip of the catheter and is for use with femoral guiding catheters.

Proximal Adaption

A two-arm adapter is attached to the proximal end of the outer member shaft and allows access to the two lumens formed by the inner and outer members. The side port of the two-arm adapter accesses the balloon inflation/deflation lumen between the inner and outer member. The central port is aligned with the lumen of the inner member where the guide wire is placed. A polyolefin elastomer strain relief is placed onto the outer member. The outer member is thermally bonded to a polyolefin shrink tubing. The polyolefin elastomer strain relief is attached to the two-arm adapter using a mechanical/interference seal. The outer member and inner member are bonded to the two-arm adapter using Loctite 3201 UV adhesive.

Summary

The TREK OTW and MINI TREK OTW are discussed in more detail on the following pages. The tables provide an overview of the design and material components of the TREK OTW and MINI TREK OTW compared to the currently approved VOYAGER® OTW and VOYAGER® NC Coronary Dilatation Catheters. Where components of the TREK OTW and MINI TREK OTW are different from the VOYAGER® OTW and

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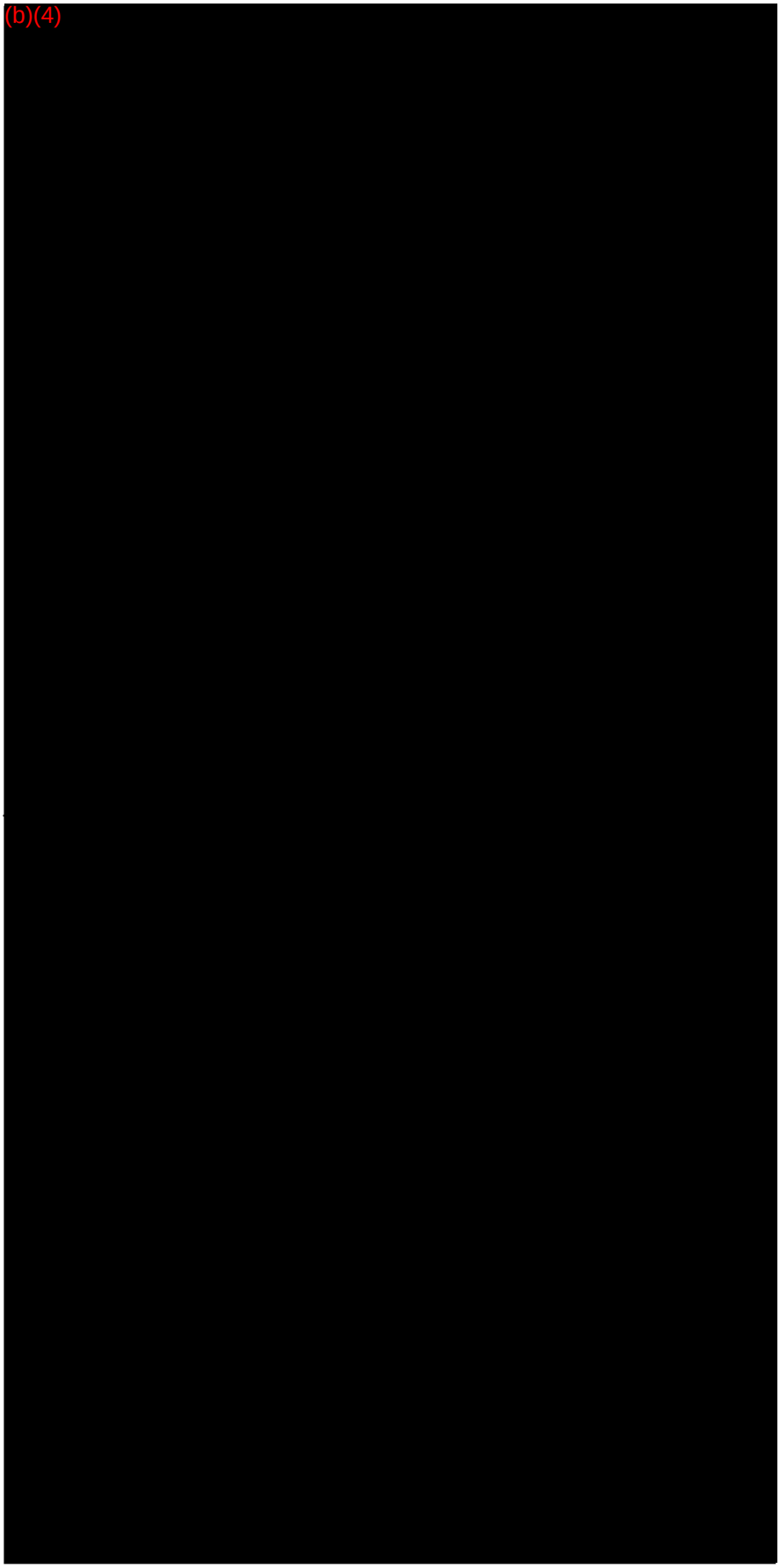
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VOYAGER® NC, these differences are highlighted by ***bold italic*** type. **Table 4-1** provides design comparisons and **Table 4-2** provides material comparisons for these devices. **Figure 4-1**, **Figure 4-2**, and **Figure 4-3** provide detailed drawings of the components of the TREK OTW and MINI TREK OTW.

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4.2 MANUFACTURING

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are designed and manufactured at the Abbott Vascular facilities located in Temecula, California.

- Abbott Vascular
  26531 Ynez Road
  Temecula, CA 92591
  FDA Establishment Registration Number: 2024168

As with the TREK RX and MINI TREK RX, the manufacturing, packaging, quality, and sterilization processes are defined by Manufacturing Process Instructions (MPI), Quality Specifications (QS), and Standard Operating Procedures (SOP). These documents establish the operating procedures and parameters ensuring conformance to product specifications. These documents are released, distributed and changed in accordance with document control procedures.

As with the TREK RX and MINI TREK RX, the assembly, quality inspection, packaging, storage, distribution and documentation of components, subassemblies and final product comply with current Quality System Regulations (QSR) as cited in 21 CFR 820.

4.2.1 Manufacturing Environment Controls

The manufacturing environment controls for the TREK OTW and MINI TREK OTW are identical to those described in this same section of the PMA Supplement (P810046/S235) for the TREK RX and MINI TREK RX (pages 4-13 through 4-14).

4.2.2 Manufacturing Process Instructions

A manufacturing glossary is provided, **Table 4-3**, to aid with manufacturing description terms for the TREK OTW and MINI TREK OTW.

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Table 4-3 Glossary of Manufacturing Terms

Term	Definition
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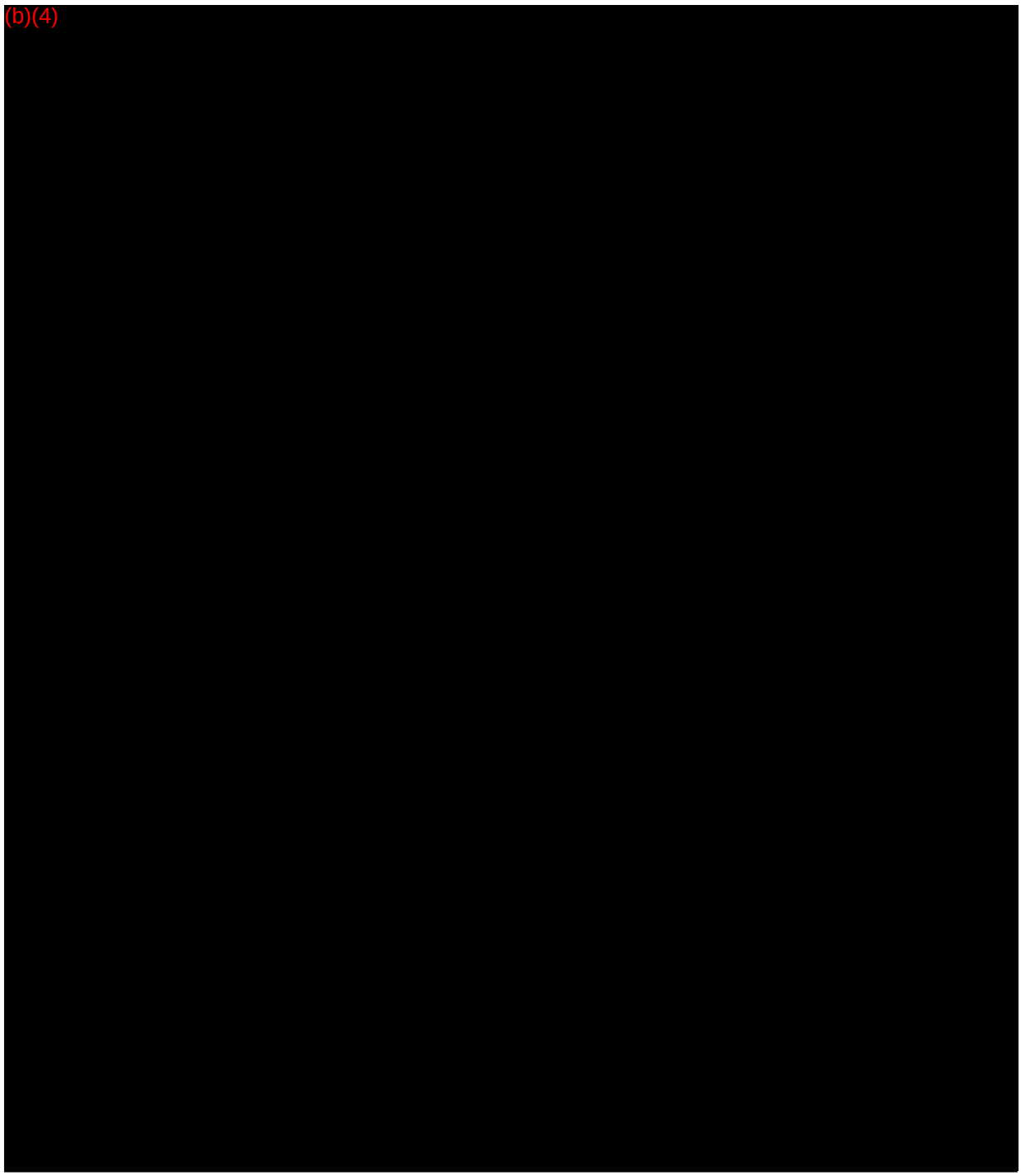
The manufacturing process instructions for the TREK OTW and MINI TREK OTW can be divided into the subassembly steps listed below and are illustrated by the manufacturing process diagram, **Figure 4-4**. A detailed outline of the manufacturing process is also provided. Processes which are identical to those of the TREK RX and MINI TREK RX are highlighted below and in **Figure 4-4** in bold italics.

- ***Balloon Processing***
- ***Inner Member Processing***
- ***Tip Processing***
- ***Inner Member to Tip Seal and Marker Attachment***
- ***Distal Blown Outer Member Processing (DBOM)***
- ***Balloon Trim and Proximal Seal***
- Proximal Outer Member Processing
- Mid-Lap Joint Processing
- Distal Subassembly Processing
- Proximal Adaption
- ***Finished Device Testing***
- ***Distal Coating Processing and Balloon Sheathing***
- ***Inner Member Coating***
- ***Packaging***
- ***Finished Device Audit***
- ***Sterilization***

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Figure 4-4 Manufacturing Process Diagram
TREK OTW and MINI TREK OTW Coronary Dilatation Catheters

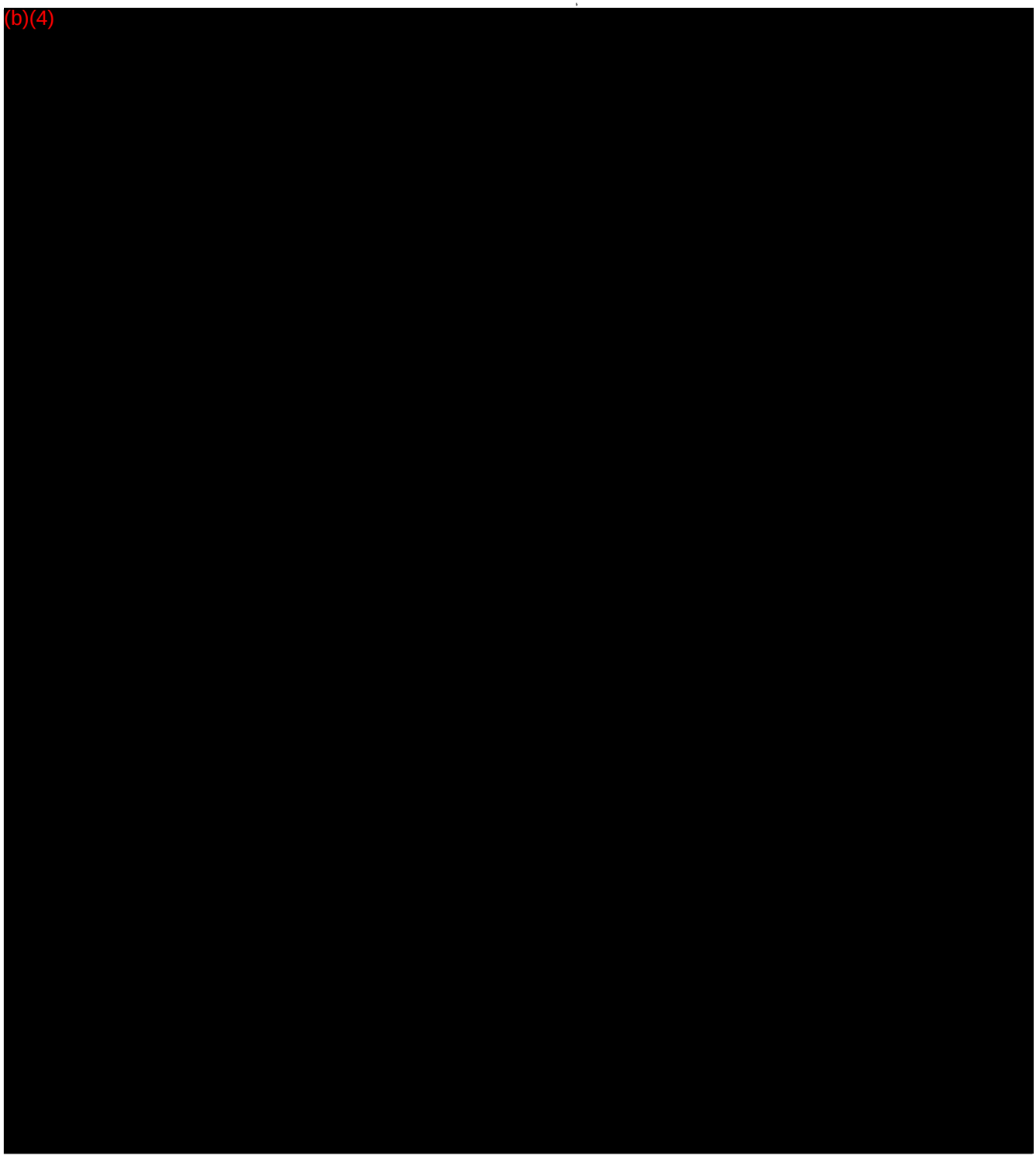


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Each subassembly step and the final assembly step involve several different operations as provided on the following pages.

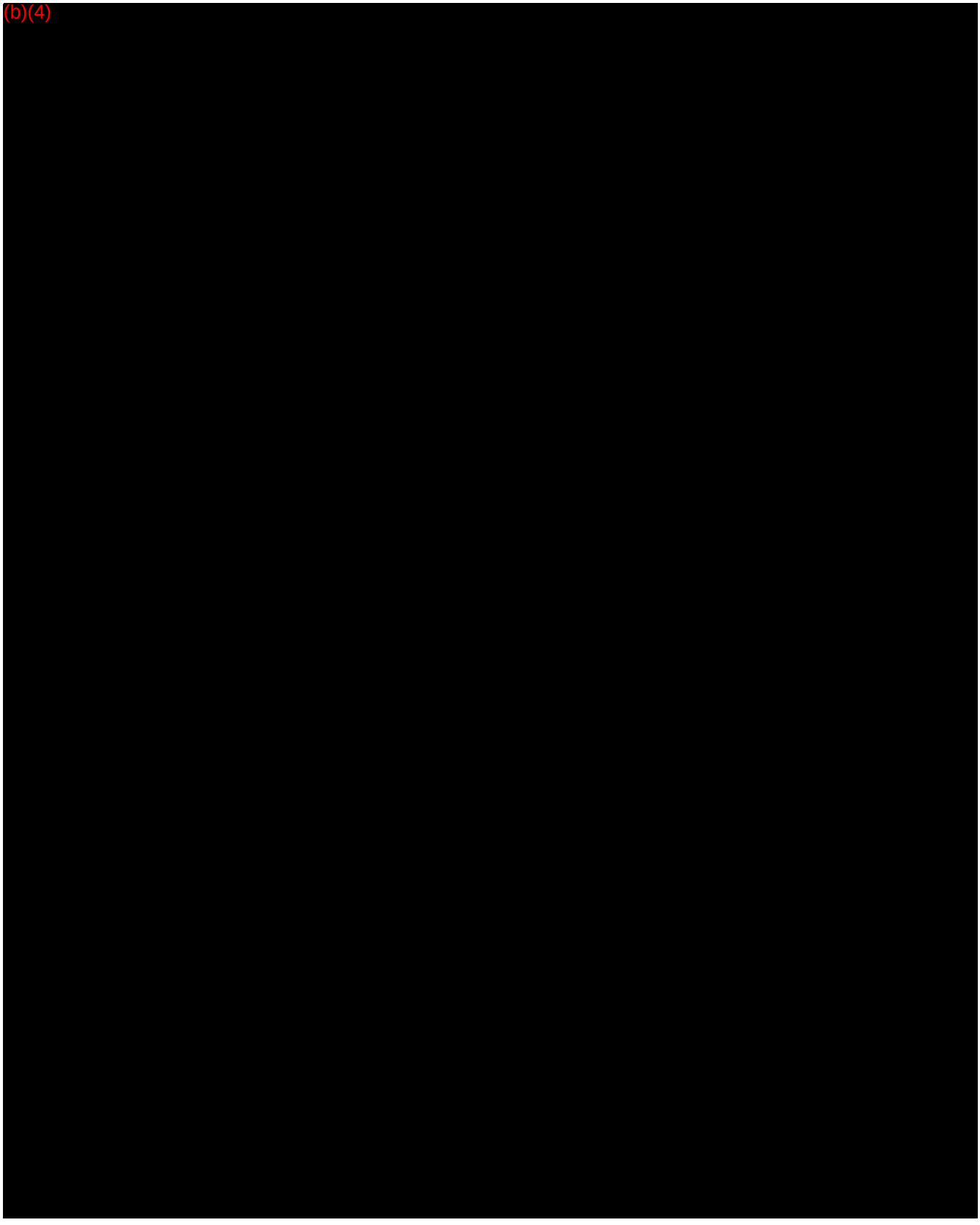
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Finished Device Audit
Identical to TREK RX and MINI TREK RX

Sterilization
Identical to TREK RX and MINI TREK RX

4.2.3 Inspection and Audit Plan

The inspection and audit plan for the TREK OTW and MINI TREK OTW are identical to those described in this same section of the PMA Supplement (P810046/S235) for the TREK RX and MINI TREK RX (pages 4-24 through 4-26).

4.3 PACKAGING INFORMATION

The packaging materials and processes for the TREK OTW and MINI TREK OTW are identical to those described in this same section of the PMA Supplement (P810046/S235) for the TREK RX and MINI TREK RX (pages 4-26 through 4-27).

Package integrity information is discussed in **Attachment 20, Section 6.3**.

4.4 STERILIZATON INFORMATION

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are sold sterile and for single use only. The sterilization method and cycle for the TREK OTW and MINI TREK OTW are identical to those described in this same section of the PMA Supplement (P810046/S235) for the TREK RX and MINI TREK RX (pages 4-28).

Sterilization testing information is provided in **Attachment 20, Section 6.2**.

4.5 SHELF LIFE INFORMATION

Samples of the TREK OTW and MINI TREK OTW were subjected to accelerated aging, following a similar protocol to that of the TREK RX and MINI TREK RX, and evaluated to assure adherence to the established product specification. Where device design and manufacturing is identical to the TREK™ RX and MINI TREK™ RX, testing previously preformed and included in P810046/S235 is leveraged and additional testing of the OTW version of the device was not repeated. Where the OTW catheter differs from the RX catheter, testing has been performed. The data collected to date ensure a minimum product shelf life of six (6) months. The shelf life will be extended up to three years, as sufficient accelerated aging data is

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collected, based on the same test protocol and acceptance criteria which has been included in **Attachment 20, Section 6.4**, *In Vitro* Bench Testing. Abbott Vascular will notify FDA via a periodic report to P810046 when the shelf life is extended. Summaries of the real time aging test results will also be included in periodic reports as testing is completed.

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SECTION 5

PERFORMANCE STANDARDS

Action taken to comply with Section 514 (Performance Standards) of the Federal Food, Drug, and Cosmetic Act:

As of this time, performance standards have not been established for coronary dilatation catheters for percutaneous transluminal coronary angioplasty.

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SECTION 6

TECHNICAL INFORMATION

Section 6 discusses the following technical studies that were either repeated or leveraged for the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters.

6.1 Biocompatibility Testing
6.2 Sterilization Testing
6.3 Packaging Integrity Test
6.4 *In vitro* Bench Testing
6.5 Risk Analysis

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6.1 BIOCOMPATIBILITY TESTING

Biocompatibility in testing was conducted in accordance with ISO 10993-1:2003, *Biological evaluation of medical devices – Part 1: Evaluation and testing*, and *Draft Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, May 30, 2008. The results of this testing found the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters to be acceptable for clinical use. All tests were conducted in compliance with Good Laboratory Practices regulations (21 CFR §58 and 40 CFR §160).

The catheter chassis materials and manufacturing process are identical for all balloon sizes, however, two balloon materials are used. The balloon material for the 2.25 mm through 5.00 mm balloon diameters, TREK OTW, is comprised of a co-extrusion of Pebax 70D over Pebax 63D, which remain as two distinct layers in the balloon. The balloon material for the 1.50 mm through 2.00 mm balloon diameters, MINI TREK OTW, is comprised of Pebax 70D. These balloons, along with the distal portion of the device, are identical to those of the MINI TREK RX and TREK RX devices currently under review (P810046/S235, submitted March 19, 2010). Although the TREK family of Coronary Dilatation Catheter has two different balloons, biocompatibility testing was conducted only on catheters of one balloon type. The balloon type tested is manufactured from co-extruded Pebax 63D and Pebax 70D which remain as two distinct layers in the completed balloon. The balloon type which was not tested is comprised of only the Pebax 70D material. Since the co-extruded balloon type includes the Pebax 70D material as a distinct layer in the balloon, the balloon type comprised only of Pebax 70D was not tested.

Biocompatibility testing reported in this supplement was conducted at the following locations:

- NAMSA, 6750 Wales Road, Northwood, OH 43619
- Abbott Vascular, 26531 Ynez Road, Temecula, CA 92591

The biocompatibility tests and their results are shown in the **Table 6-1**. The test protocols and results are provided in **Appendix A20-1**.

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The responses to biocompatibility related deficiencies for TREK RX and MINI TREK RX, provided in Attachment A1 through Attachment A7, include information for TREK OTW and MINI TREK OTW.

The *Draft Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters* recommends the inclusion of *in vivo* thromboresistance as part of hemocompatibility testing. Abbott Vascular has not performed *in vivo* thromboresistance testing based upon prior material usage and similar manufacturing processes for these materials.

In addition to the biocompatibility tests required by ISO 10993-1, additional bacterial endotoxins testing was conducted in accordance with the procedure for LAL Bacterial Endotoxins Test for Medical Devices: Chromogenic Method. This procedure parallels USP <85> *Bacterial Endotoxins Test*, a version of which is contained in Appendix B of the FDA Guidance Document, "*Guideline on Validation of the Limulus Amoebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices.*" The test samples are non-pyrogenic if the nominal reading is less than 0.5 EU/mL.

Abbott Vascular previously received questions from FDA regarding the use of nulliparaous and non-pregnant female guinea pigs for Sensitization testing and the use of the ISO method for Material-Mediated Rabbit Pyrogen testing in connection with another submission. This additional information requested is provided below for ease of review.

No pregnant female guinea pigs were used for sensitization testing of the TREK OTW Coronary Dilatation Catheter. Females which are nulliparous and not pregnant are a requirement of ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity*. When animals are received at Pacific BioLabs, the sex of each animal is verified; and then the animals are housed by sex. Any

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females inadvertently shipped with males are euthanized upon arrival due to the potential pregnancy risk associated with cohabitation.

The Material-Mediated Rabbit Pyrogen Test for the TREK OTW was performed according to the requirements of ISO 10993-11, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*. The test article is evaluated via systemic administration of an extract for a non-endotoxin related pyrogen reaction, which is referred to as material-mediated pyrogenicity. ISO 10993-11 references USP <151> *Pyrogen Test* for dose administration and subsequent body temperature readings to assess the degree of systemic pyrogenic response. The ISO and USP methods differ in the preparation of the test articles. The differences are in the number of devices used, the use of surface area as a means of determining the volume of extraction media and the conditions under which the device is extracted. All other aspects of the test method are equivalent.

The results obtained from the biological evaluation indicate that the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters do not introduce any safety risks associated with their introduction into the body. The TREK OTW and MINI TREK OTW are acceptable for short-term use in the cardiovascular system.

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6.2 STERILIZATION

Ethylene Oxide Sterilization Cycle

The sterilization cycle and sterilization cycle to be used for the TREK OTW and MINI TREK OTW is identical to that of the TREK RX, MINI TREK RX and other currently marketed devices approved under P810046, including the VOYAGER OTW and VOYAGER NC Coronary Dilatation Catheters.

Ethylene Oxide Residuals Testing

Ethylene oxide residual testing was conducted to demonstrate that the device is in compliance with the maximum allowable EtO and ethylene chlorohydrin (ECH) as required by ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide residuals*. The maximum average daily allowable residuals according to ISO 10993-7 for limited exposure devices are 4 mg for EtO and 9 mg for ECH. Test results for ethylene glycol (EG) are also included although there are not maximum allowable limits established by the standard.

Table 6-2 below provides a summary of the EtO residual testing conducted for the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters.

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The results of the EtO residual testing show that upon completion of aeration and sterility release following sterilization, the TREK OTW and MINI TREK OTW meet the ISO 10993-7 requirements for both ethylene oxide and ethylene chlorohydrin residuals.

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6.3 PACKAGE INTEGRITY TESTING

The TREK OTW and MINI TREK OTW packaging is identical to that of the TREK RX and MINI TREK RX with the exception that the flushing tool and catheter clip are not included with the device as these accessories are not required for use with over-the-wire devices.

Packaging integrity validation has been performed in accordance with the requirements of ISO 11607-1:2006, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*, and ISO 11607-2:2006, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*, and this information was included in P810046/S235 for the TREK RX and MINI TREK RX. This validation is composed of three components, according to the requirements of ISO 11607-1 and ISO 11607-2: 1) process validation which tests the seal strength at the nominal, upper and lower parameters of the sealing process; 2) design qualification which tests whole package integrity and seal strength at the upper and lower limits of the package seal process parameters following package sterilization and transportation conditioning; and, 3) material qualification which tests the package material for degradation over time, including potential sterilization effects, throughout the product shelf-life.

The test article, representing the worst case for both a rapid exchange and over-the-wire catheter, included the following:

- The TREK OTW catheter as a worst case catheter design due to the side arm proximal adapter which is angled in comparison to the straight proximal adapter of the TREK RX.

- The flushing tool and catheter clip which are included with rapid exchange catheter designs as worst case due to the additional weight included within the sterile barrier.

Completed accelerated aging testing of the packaging support up to a three (3) year shelf life. Real-time aging is currently being conducted following the identical package integrity protocol included in P810046/S235 for the TREK RX and MINI TREK RX.

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6.4 *In Vitro* Bench Testing

The TREK OTW and MINI TREK OTW are similar in design and materials to the VOYAGER® OTW (P810046/S222, approved September 27, 2007) and identical to the distal portion, from tip to mid-lap joint, of the TREK RX and MINI TREK RX.

The TREK RX and MINI TREK RX were subjected to *in vitro* bench testing to assure conformance with the requirements set forth in *Draft Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* May 30, 2008. Where design and manufacturing process are identical to the TREK RX and MINI TREK RX, the *in vitro* bench testing is being leveraged from the previously submitted TREK RX and MINI TREK RX data.

The results for the tests listed in the table below are included in more detail with each test on the following pages.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The sizes selected for testing were based on product design, materials, and test characteristic, as described in more detail with each test procedure and its results. Additionally, **Attachment 8**, provides further rationale for size selection for all *in vitro* bench tests performed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

ACCELERATED AGING TEST PROTOCOL

Purpose

The purpose of this protocol is to outline and document the accelerated aging conditions and functional testing necessary to evaluate any degradation in the materials of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters over a three (3) year shelf life.

The aging testing will demonstrate the following:

- The product conforms with the labeled product shelf life by meeting its functional and performance specifications after exposure to aging conditions.
- The product packaging adequately protects the device during simulated handling and storage.

The device will function as intended after exposure to extreme temperature conditions for relatively short periods of time, as might occur during normal transportation processes.

Materials

- EtO Sterilized (one time) TREK OTW and MINI TREK OTW Coronary Dilatation Catheters
- Environmental Chamber
- Other materials as listed under each test performed

Discussion

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

ACCELERATED AGING TEST PROTOCOL - *Continued*

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

ACCELERATED AGING TEST PROTOCOL - *Continued*

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

ACCELERATED AGING TEST PROTOCOL - *Continued*

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER PREPARATION

Purpose

To evaluate the ease of preparing the device using the double-negative aspiration method.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 5.00 mm x 15 mm
- Aged, EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.25 mm x 30 mm
- 60% contrast medium, diluted 1:1 with water
- 20 cc syringe
- Inflation device

Discussion

Catheter Preparation is performed on a device with a folded balloon. During the balloon fold manufacturing process, the system is held under negative pressure to ensure the balloon folds wrap tightly around the inner member, effectively eliminating any volume of air within the balloon. Therefore, balloon size does not affect the ability to prep the device.

Catheter shaft design affects the ability for the contrast to flow through the inter-lumen space during prep. One size from each chassis configuration, for both baseline and aged samples, was tested to represent all sizes in the matrix.

Refer to **Attachment 9** for additional information regarding sample size selection for Catheter Preparation.

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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CATHETER PREPARATION - *Continued*

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER PROFILE TEST:
CROSSING PROFILE AND REFOLDED PROFILE

Purpose

To determine the crossing profiles and refolded balloon crossing profiles of the device.

Refolded balloon crossing profiles are being leveraged from testing of the TREK RX and MINI TREK RX. Refer to P810046/S235, Section 6.4, page 6-35 through page 6.39, for these leveraged test results and conclusions.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.00 mm x 30 mm 2.25 mm x 30 mm
  5.00 mm x 15 mm
- Aged, EtO Sterilized TREK OTW and MINI TREK OTW
  2.00 mm x 30 mm 5.00 mm x 15 mm
- Guide Wire (0.014 inch)
- Profile block
- Inflation device
- Heated water bath

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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CATHETER PROFILE TEST: CROSSING PROFILE AND REFOLDED PROFILE – *Continued*

Procedure

(b)(4)

Results

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER PROFILE TEST:
CROSSING PROFILE AND REFOLDED PROFILE - *Continued*

Results,
Continued

(b)(4)

[redacted]

Conclusion

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

BALLOON INFLATION / DEFLATION TIMES

(b)(4)



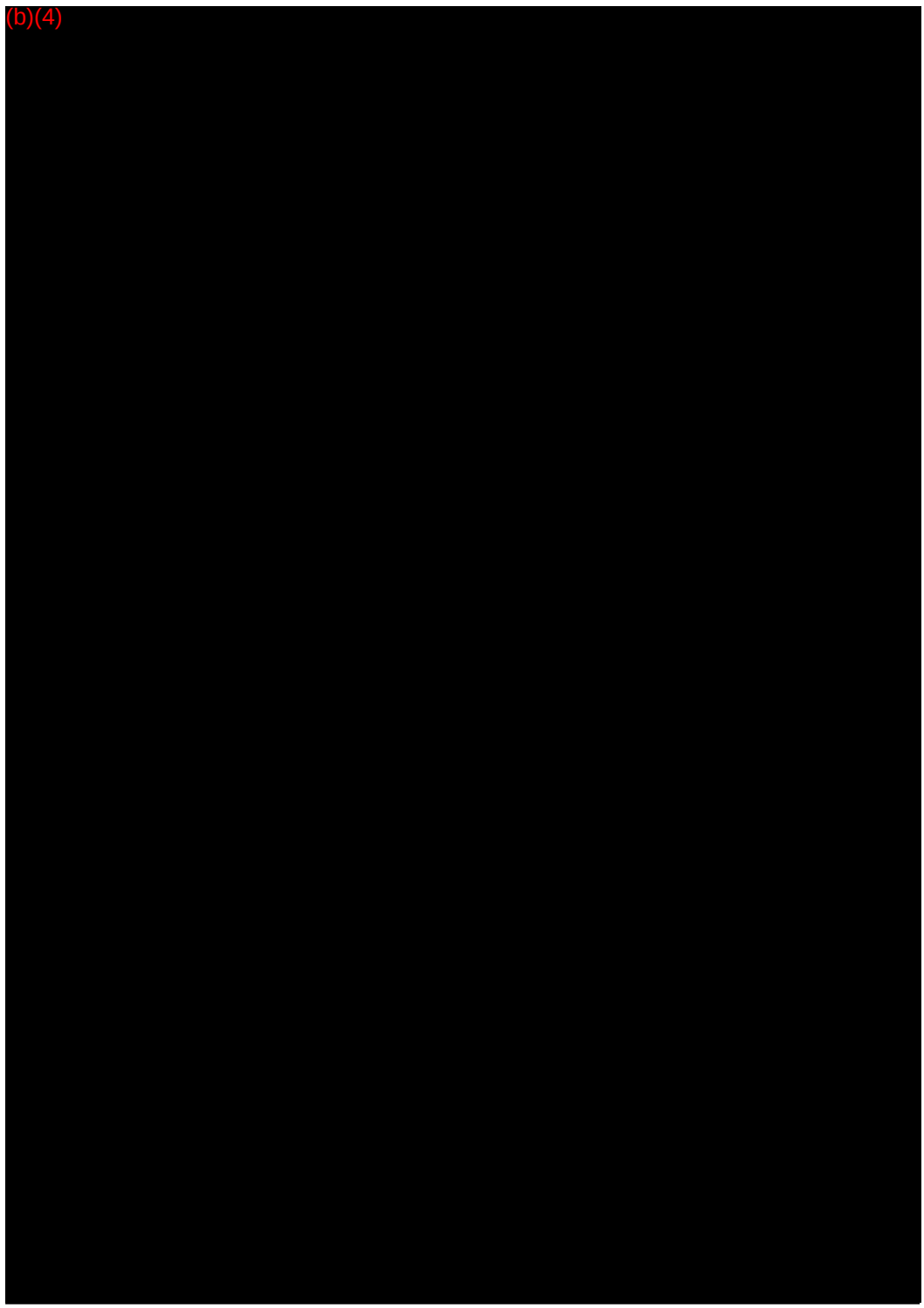
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

BALLOON INFLATION / DEFLATION TIMES - *Continued*

Results

(b)(4)



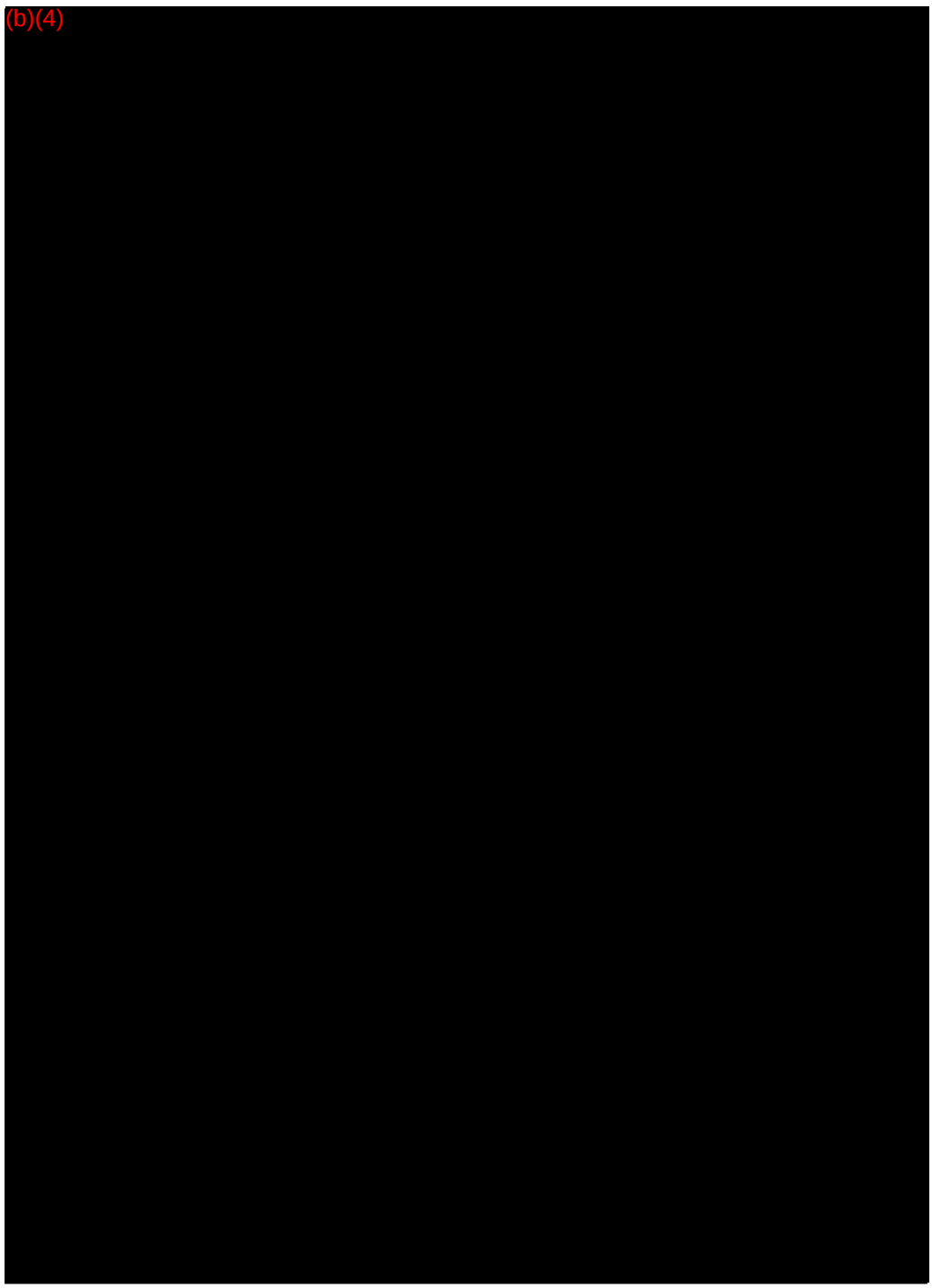
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

BALLOON INFLATION / DEFLATION TIMES - *Continued*

Results,
Continued

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

BALLOON INFLATION / DEFLATION TIMES - *Continued*

Conclusion The balloon inflation and deflation times of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are functionally acceptable and within the product specifications. The TREK OTW and MINI TREK OTW maintain this functional ability through its current shelf life of six (6) months.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

BALLOON FATIGUE

Purpose

To statistically demonstrate that at a 95% confidence level, at least 90% of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters will sustain 20 repeated inflations to the rated burst pressure, 206 psi (14 atm), and held for 30 seconds at the rated burst pressure for each inflation.

Balloon Fatigue is being leveraged from testing of the TREK RX and MINI TREK RX. Refer to P810046/S235, Section 6.4, page 6-44 through page 6-58, for these leveraged test results and conclusions. Additional information provided, as a result of the deficiency received, is included in **Attachment 11**.

BALLOON FATIGUE WITHIN A STENT

Purpose

To statistically demonstrate that at a 95% confidence level, at least 90% of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters will sustain 10 repeated inflations to the rated burst pressure, 206 psi (14 atm), and held for 30 seconds for each inflation when pressurized within a stent.

Balloon Fatigue Within a Stent is being leveraged from testing of the TREK RX and MINI TREK RX. Refer to P810046/S235, Section 6.4, page 6-59 through page 6-71, for these leveraged test results and conclusions. Additional information provided, as a result of the deficiency received, is included in **Attachment 12**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

BALLOON RUPTURE

Purpose

To determine the rupture pressures of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters and to statistically demonstrate that at a 95% confidence level, 99.9% of the catheters will not rupture at or below 206 psi (14 atm) for all balloon diameter sizes.

Balloon Rupture is being leveraged from testing of the TREK RX and MINI TREK RX. Refer to P810046/S235, Section 6.4, page 6-72 through page 6-78, for these leveraged test results and conclusions. Additional information provided, as a result of the deficiency received, is included in **Attachment 13**.

BALLOON RUPTURE WITHIN A STENT

Purpose

To determine the rupture pressure of the TREK RX and MINI TREK Coronary Dilatation Catheters and to statistically demonstrate that at a 95% confidence level, 99.9% of the catheters will not rupture at or below 206 psi (14 atm) when pressurized within a stent for all balloon diameter sizes.

Balloon Rupture Within a Stent is being leveraged from testing of the TREK RX and MINI TREK RX. Refer to P810046/S235, Section 6.4, page 6-79 through page 6-84, for these leveraged test results and conclusions. Additional information provided, as a result of the deficiency received, is included in **Attachment 14.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

BALLOON COMPLIANCE

Purpose

To determine the inflation pressure and balloon diameter relationship of the device.

Balloon Compliance is being leveraged from testing of the TREK RX and MINI TREK RX. Refer to P810046/S235, Section 6.4, page 6-85 through page 6-97, for these leveraged test results and conclusions. Additional information provided, as a result of the deficiency received, is included in **Attachment 15.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT FATIGUE

Purpose

To statistically demonstrate that at a 95% confidence level, at least 90% of the MINI TREK OTW and TREK OTW shafts will sustain 20 repeated inflations to the rated burst pressure.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.25 mm x 30 mm
- Aged, EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.25 mm x 30 mm
- Pressure tester
- Balloon holding fixture
- Water bath
- 0.014" guidewire or packaging stylet
- Balloon sheath

Discussion

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT FATIGUE - *Continued*

(b)(4)



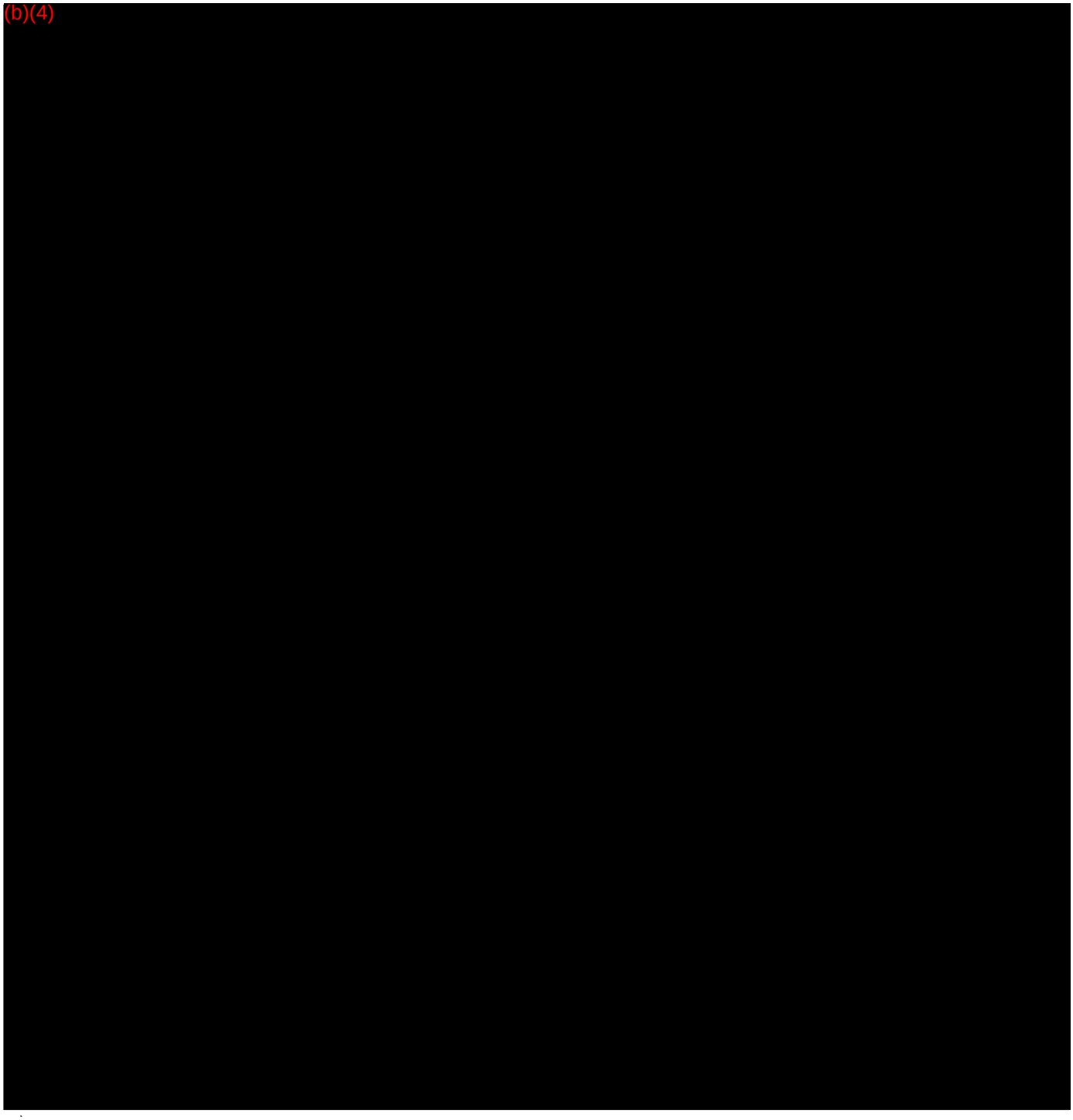
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT FATIGUE - *Continued*

(b)(4)

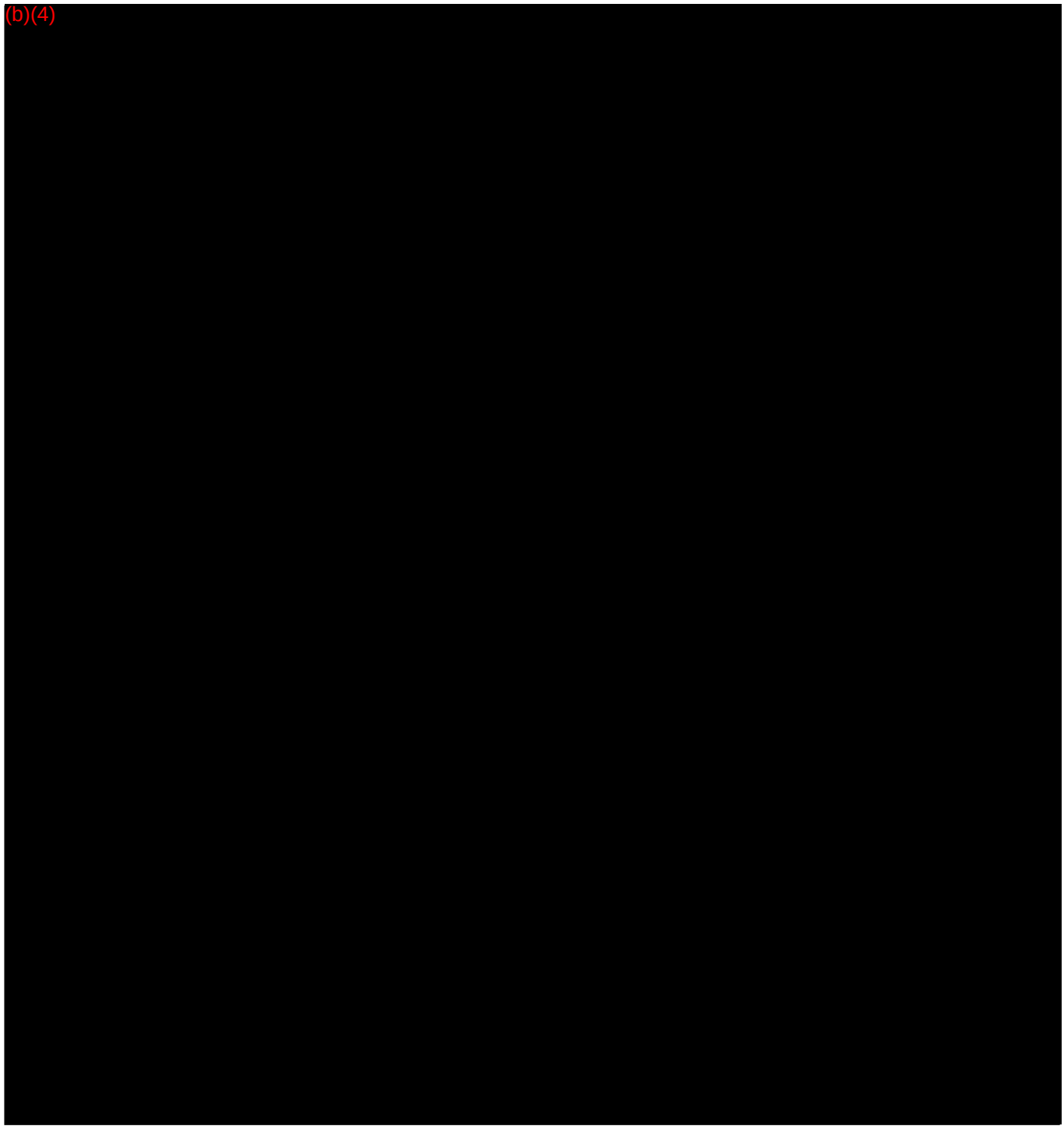


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT FATIGUE - *Continued*

(b)(4)

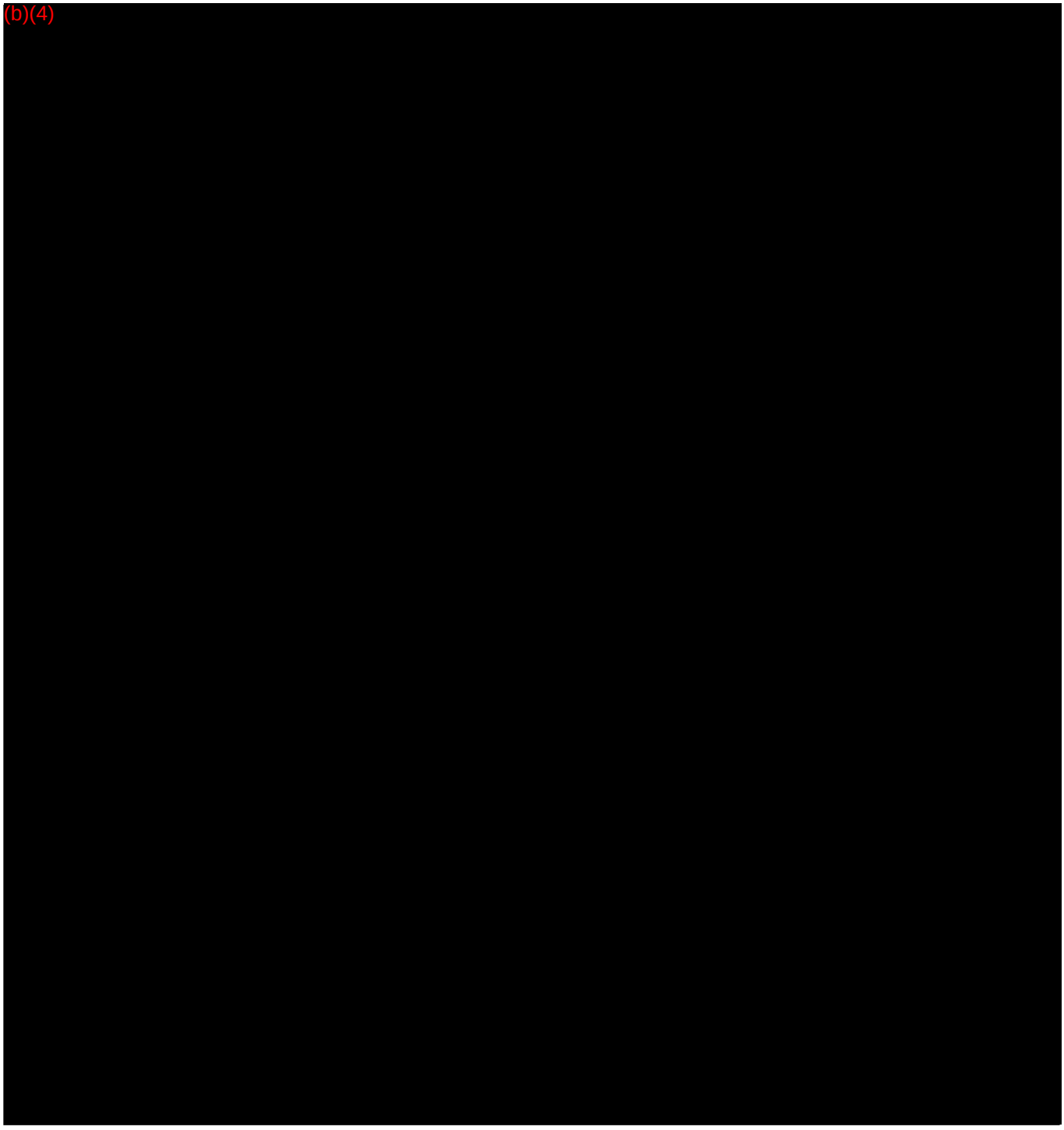


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT FATIGUE - *Continued*

(b)(4)

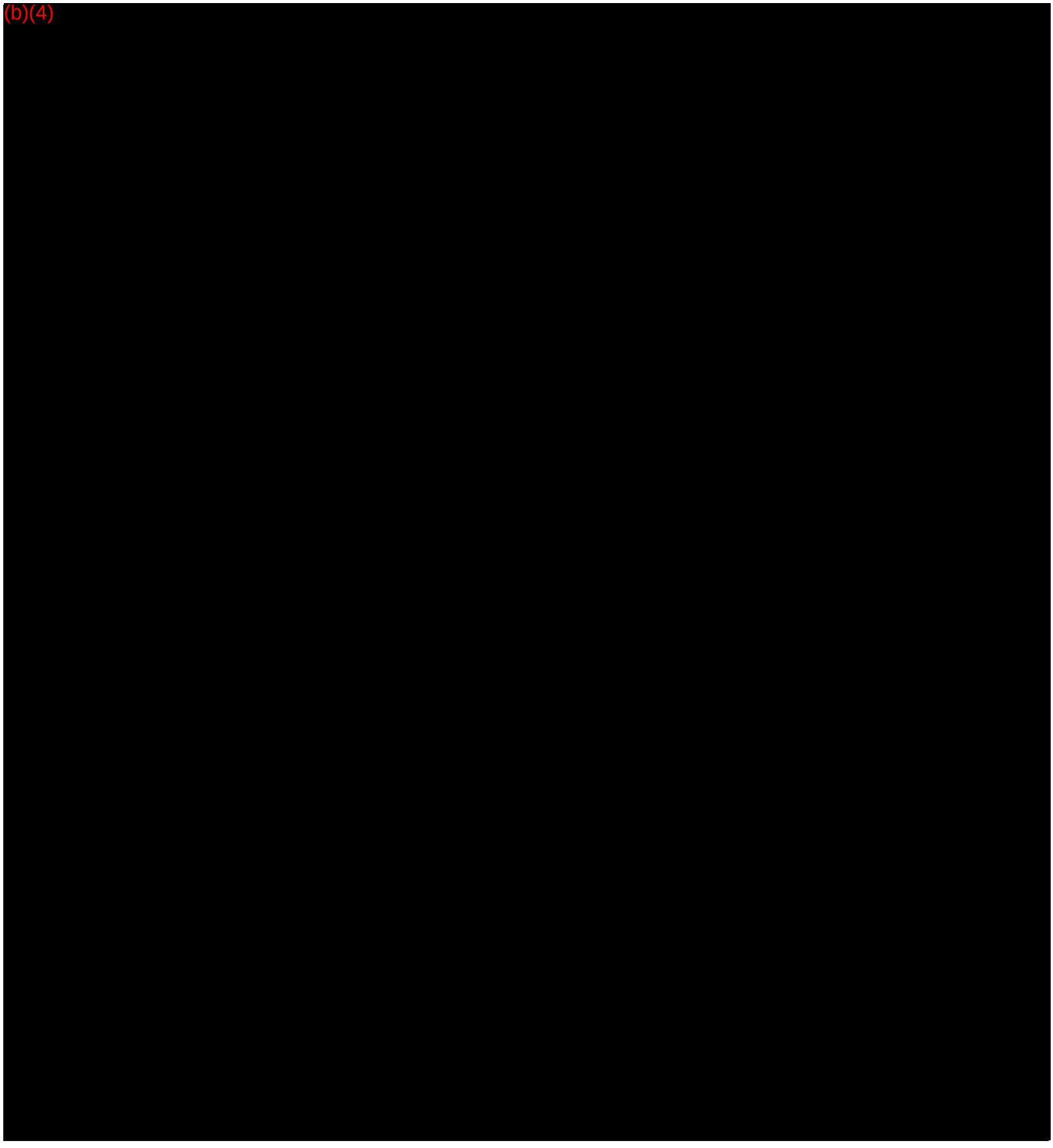


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CATHETER SHAFT FATIGUE - *Continued*

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT FATIGUE - *Continued*

Results

Conclusion Based on the catheter shaft fatigue test results and statistical analysis, at a 95% confidence level, at least 90.0% of the TREK OTW and MINI TREK OTW catheter shafts will sustain 20 repeated inflations to the rated burst pressure (RBP) of 206 psi (14 atm) for 1.50 mm through 5.00 mm balloon diameter sizes. The TREK OTW and MINI TREK OTW maintain this functional ability through its current shelf life of six (6) months.

Reference *Reliability Statistics*, Robert A. Dovich, p. 21-25.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT RUPTURE

Purpose

To determine the rupture pressures of the TREK OTW and MINI TREK OTW catheter shafts, and to statistically demonstrate that a 95% confidence level, at least 99.9% of the devices will not rupture below the rated burst pressure (RPB) of 206 psi (14 atm).

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.25 mm x 30 mm
- Aged, EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.25 mm x 30 mm
- Pressure tester
- Water bath
- 0.014" guide wire
- Balloon holding fixture
- Balloon sheath

Discussion

(b)(4)

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER SHAFT RUPTURE - *Continued*

Results

(b)(4)



Conclusion

Based on the catheter shaft rupture test results, at a 95% confidence level, at least 99.9% of the TREK OTW and MINI TREK OTW catheter shafts will not rupture below the rated burst pressure (RBP) of 206 psi (14 atm) for the 1.50 mm through 5.00 mm balloon diameter sizes. The TREK OTW and MINI TREK OTW maintain this functional ability through its current shelf life of six (6) months.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SOFT TIP TO INNER MEMBER TENSILE

Purpose

To determine the tensile strength of the soft tip to inner member bond of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW
  1.50mm x 20 mm 2.00 mm x 30 mm 2.25 mm x 30 mm
  5.00 mm x 15 mm
- Aged, EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.25 mm x 30 mm
- Tensile Tester
- Water bath

Discussion

(b)(4) [redacted]

(b)(4) [redacted]

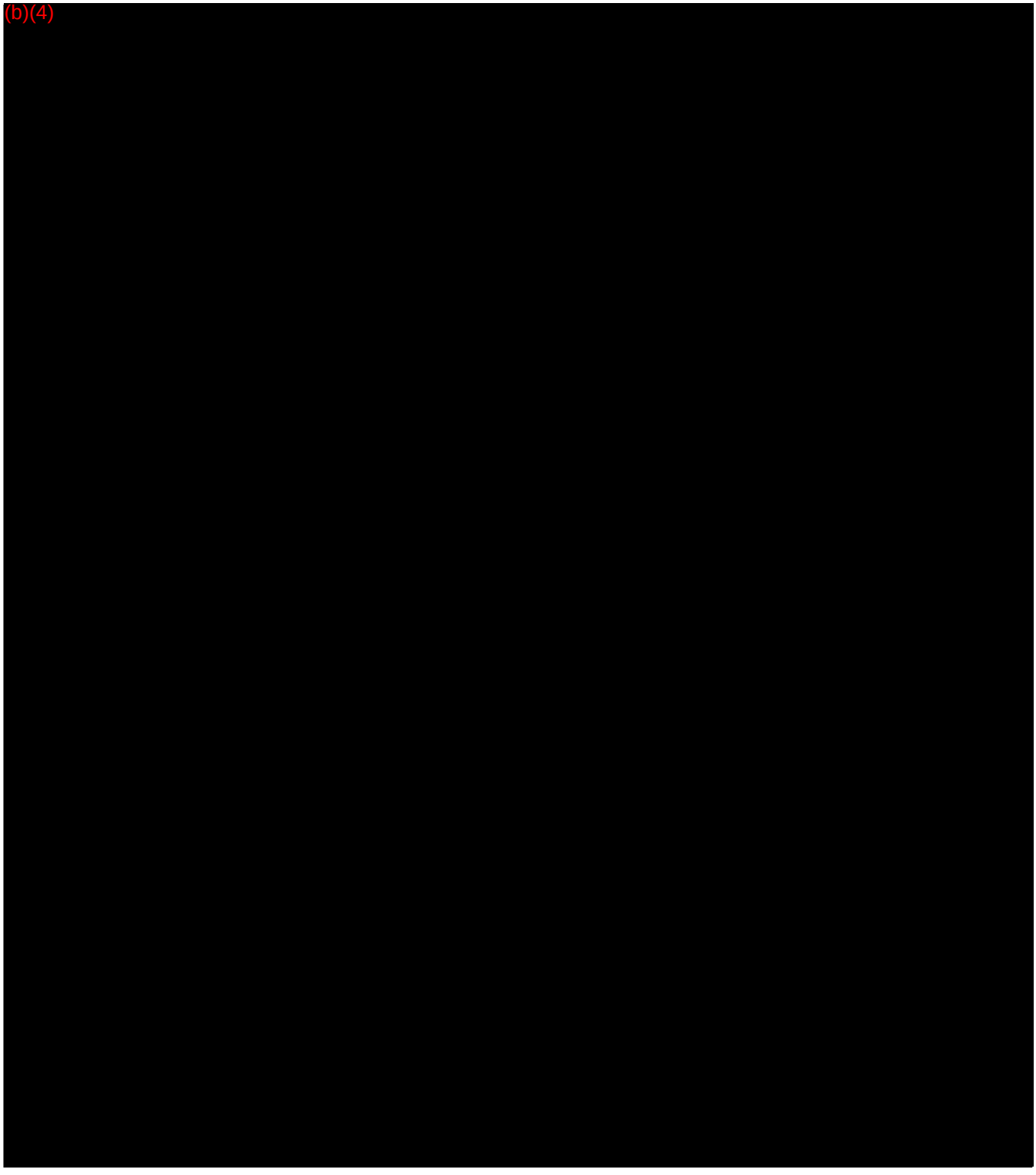
699

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SOFT TIP TO INNER MEMBER TENSILE - *Continued*

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SOFT TIP TO INNER MEMBER TENSILE - *Continued*

Conclusion Based on soft tip tensile test data, the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters with balloon diameter sizes of 1.50 mm through 5.00 mm are functionally acceptable and meet the minimum product specification of 1.12 lbf. The TREK OTW and MINI TREK OTW maintain this functional ability through its current shelf life of six (6) months.

Reference Lieberman, Gerald J. (1988), Tables for One-Sided Tolerance Limits," *Industrial Quality Control*, vol. XIV, no. 10, April, p. 8.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

PROXIMAL BALLOON SEAL TENSILE

Purpose

To determine the tensile strength of the proximal balloon seal of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.00 mm x 30 mm 2.25 mm x 30 mm
  4.00 mm x 30 mm 4.50 mm x 15 mm 5.00 mm x 15 mm
- Aged, EtO Sterilized TREK OTW and MINI TREK OTW
  1.50 mm x 20 mm 2.25 mm x 30 mm
- Tensile tester
- Water bath

Discussion

(b)(4)

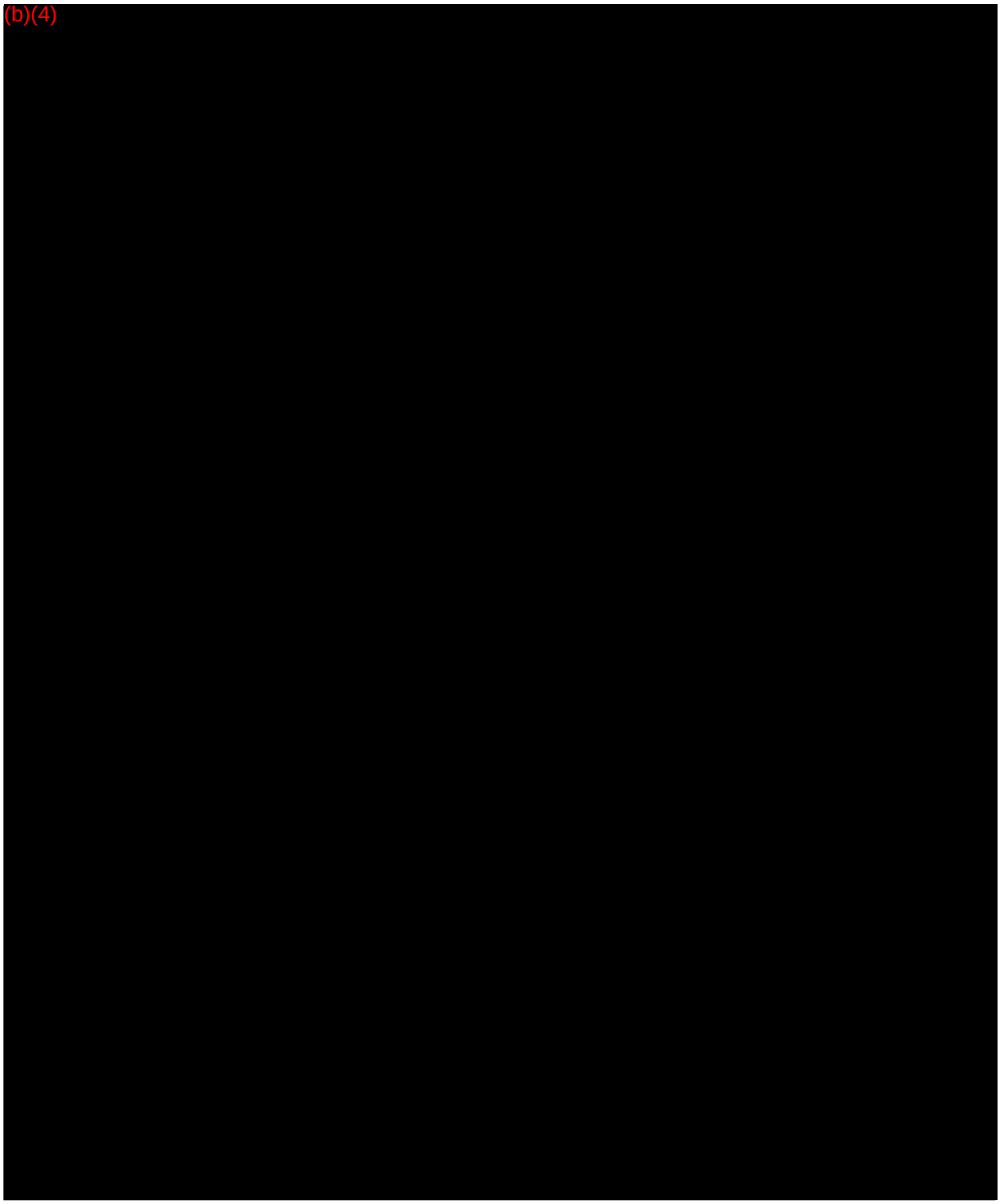
(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

PROXIMAL BALLOON SEAL TENSILE - *Continued*

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

PROXIMAL BALLOON SEAL TENSILE - *Continued*

(b)(4)



Conclusion

Based on proximal seal tensile test data, the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters with balloon diameter sizes of 1.50 mm through 5.00 mm are functionally acceptable and meet the minimum product specification of 1.1 lbf. The TREK OTW and MINI TREK OTW maintain this functional ability through its current shelf life of six (6) months.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

DISTAL CATHETER TENSILE – OUTER MEMBER TO PROXIMAL SHAFT (BOND STRENGTH)

Purpose

To determine the tensile strength of the outer member to proximal shaft bond strength of the TREK OTW and MINI TREK OTW.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW
  2.00 mm x 30 mm 5.00 mm x 15 mm
- Aged, EtO Sterilized TREK RX and MINI TREK RX
  1.50 mm x 20 mm 2.25 mm x 30 mm
- Tensile tester
- Water bath

Discussion

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

DISTAL CATHETER TENSILE – OUTER MEMBER TO PROXIMAL SHAFT - *Continued* (BOND STRENGTH)

Results

(b)(4)



(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

PROXIMAL ADAPTION TENSILE

Purpose

To determine the tensile strength of the proximal adaption portion of the device.

Materials

- EtO Sterilized MINI TREK OTW
  2.00 mm x 30 mm
- Aged, EtO Sterilized TREK OTW
  2.25 mm x 30 mm
- Tensile tester
- Water bath

Discussion

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

PROXIMAL ADAPTION TENSILE - *Continued*

(b)(4)



Conclusion

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER COATING PARTICULATE

Purpose

To determine the particle count of the TREK OTW and MINI TREK OTW Coronary Dilatation Catheters after tracking through a tortuous path and inflating inside two overlapped stents placed in a curvature bend.

Materials

- EtO Sterilized MINI TREK RX and TREK RX
  2.00 mm x 6 mm 4.00 mm x 30 mm 5.00 mm x 15 mm
- Aged, EtO Sterilized TREK RX
  4.00 mm x 30 mm
- Particle counting system
- Tortuousity fixture
- Guiding catheter
- Guide wire

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER COATING PARTICULATE - *Continued*

Discussion

(b)(4)

[redacted]

Procedure

(b)(4)

[redacted]

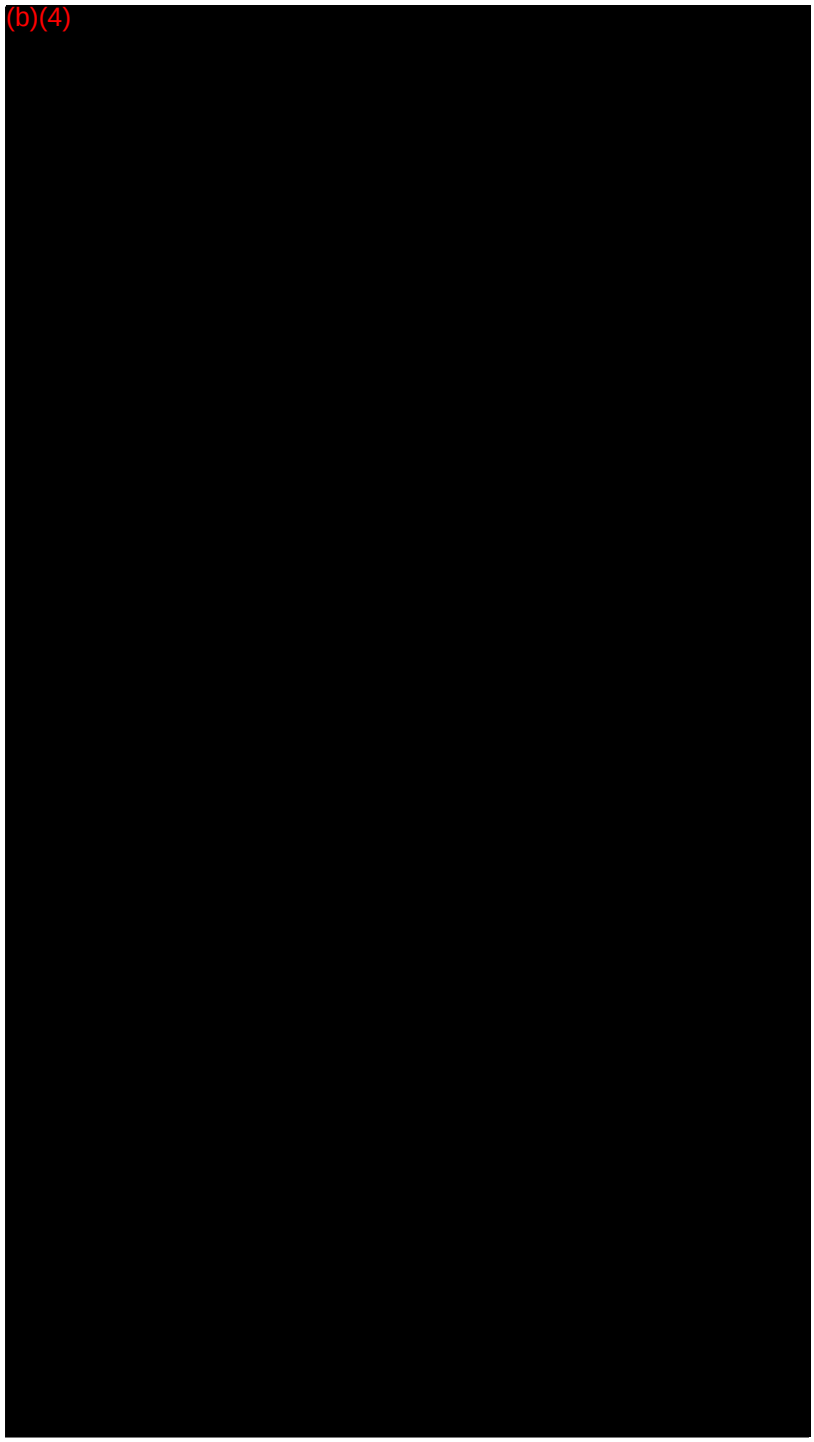
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER COATING PARTICULATE - *Continued*

Results

(b)(4)



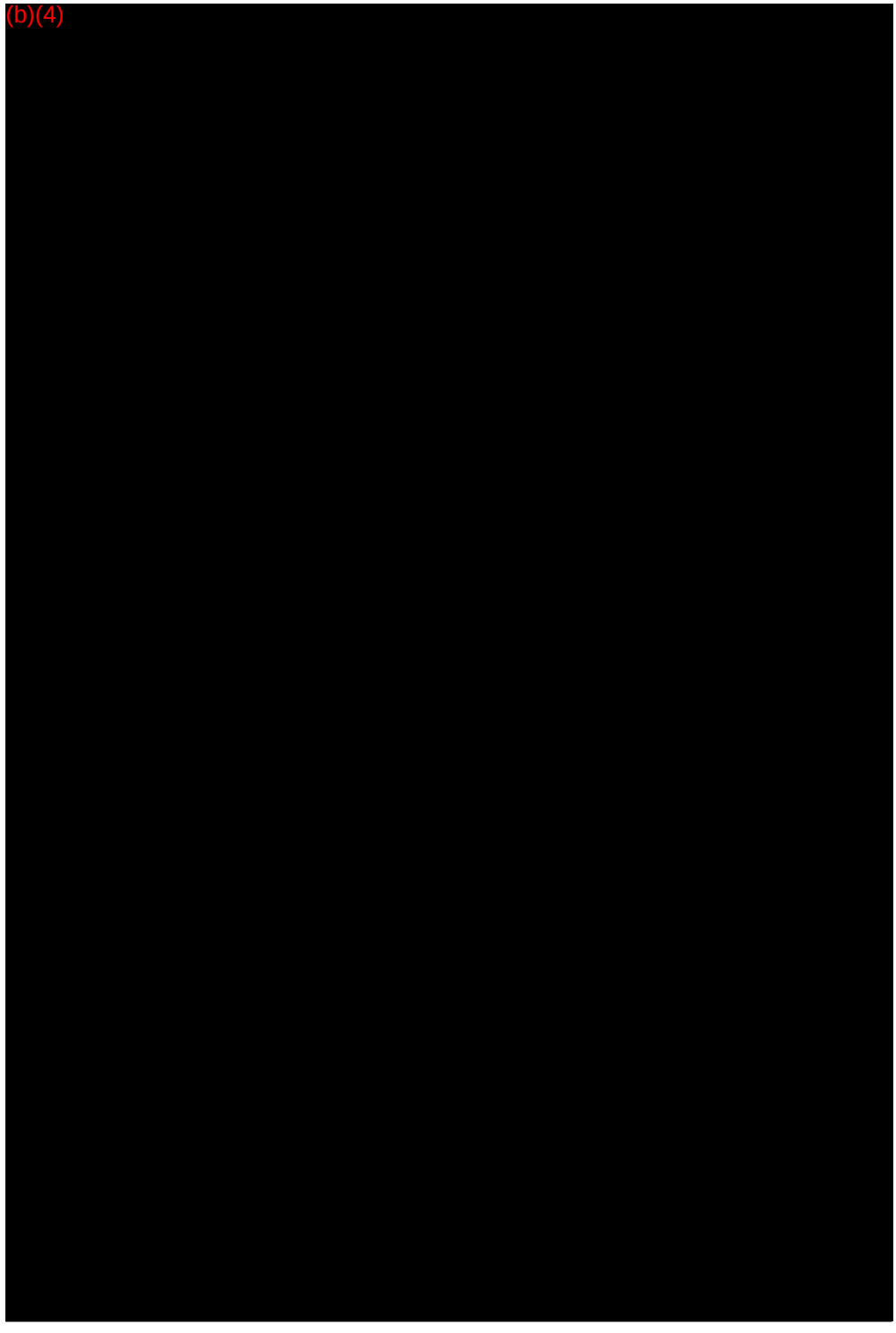
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER COATING PARTICULATE - *Continued*

Results

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER COATING PARTICULATE - *Continued*

Conclusion

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER COATING FRICTION

Purpose

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST

Purpose

To determine the minimum radius of curvature at which the catheter kinks.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW

1.50 mm x 6 mm	1.50 mm x 20 mm	2.00 mm x 6 mm
2.00 mm x 30 mm	2.25 mm x 6 mm	2.25 mm x 30 mm
3.50 mm x 30 mm	4.00 mm x 6 mm	4.00 mm x 30 mm
5.00 mm x 12 mm	5.00 mm x 15 mm	

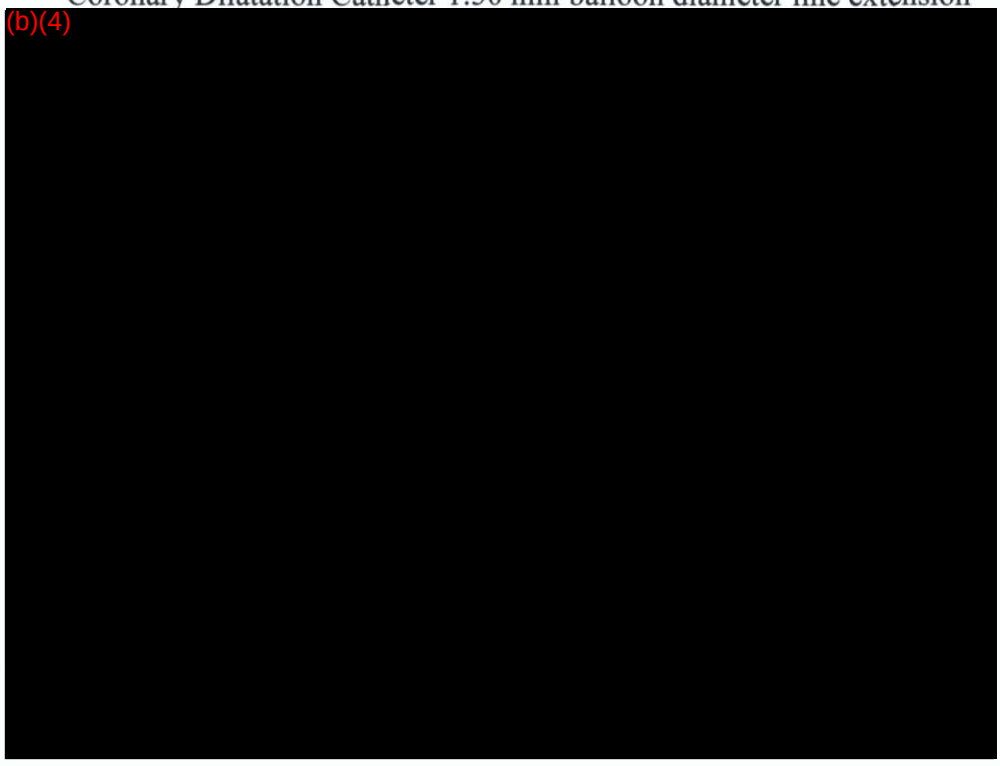
- Aged, EtO Sterilized TREK OTW and MINI TREK OTW

2.00 mm x 30 mm	5.00 x 15 mm

- Kink test fixture
- Kink test fixture, 10 degrees
- Water bath, 37ºC
- 0.014" guide wire
- Curved tip syringe
- Microscope with illuminator
- Isopropyl alcohol

Note: Test fixture is operated in a water bath maintained at 37ºC. A photo of the fixture is provided below. This fixture and test method were previously included in the submission and subsequent approval for the VOYAGER® NC Coronary Dilatation Catheter 1.50 mm balloon diameter line extension

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Discussion

(b)(4)

Procedure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Procedure

(b)(4)

[redacted]

Results

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Results,
Continued

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Results,
Continued

(b)(4)

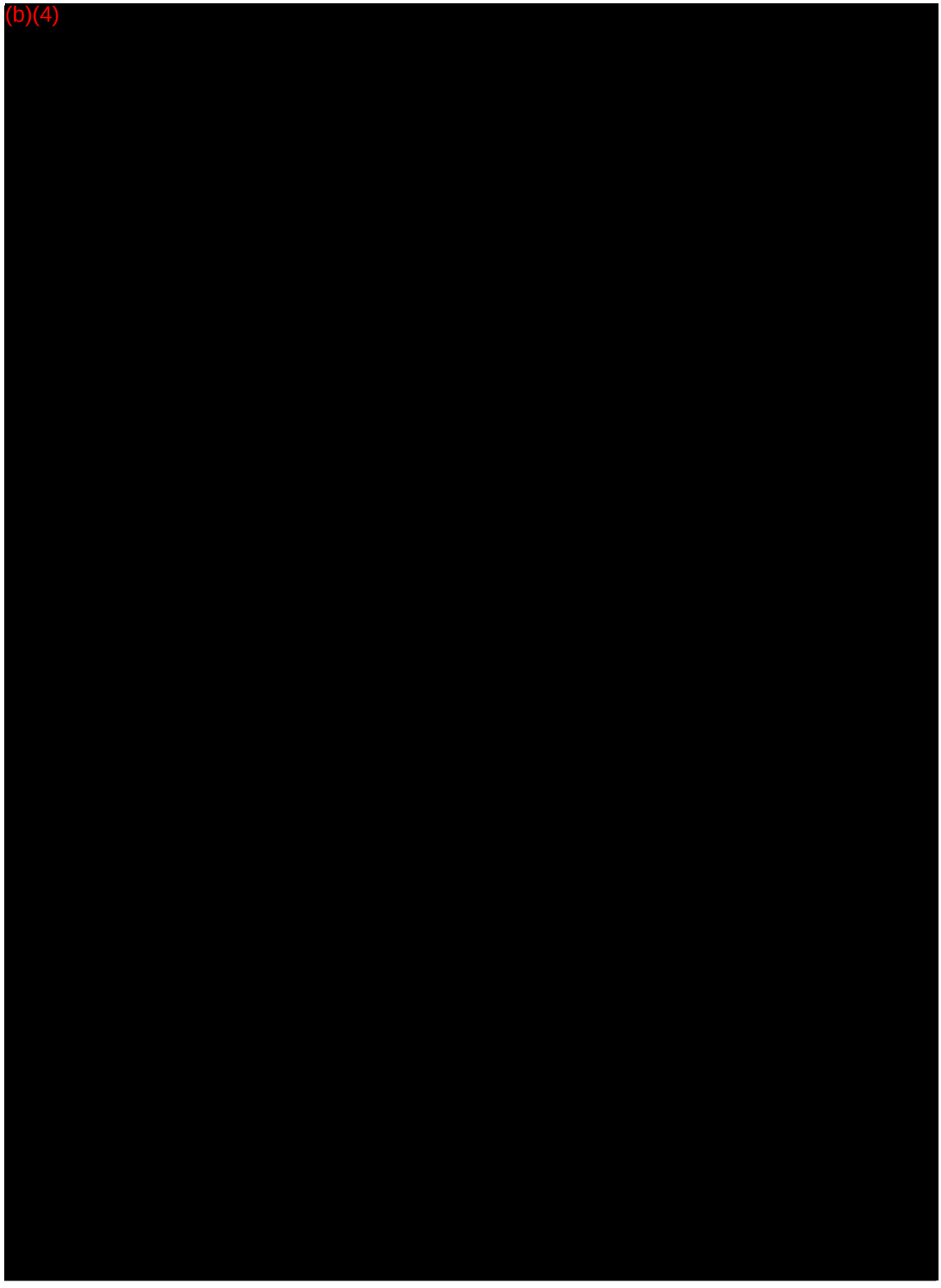
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Results,
Continued

(b)(4)



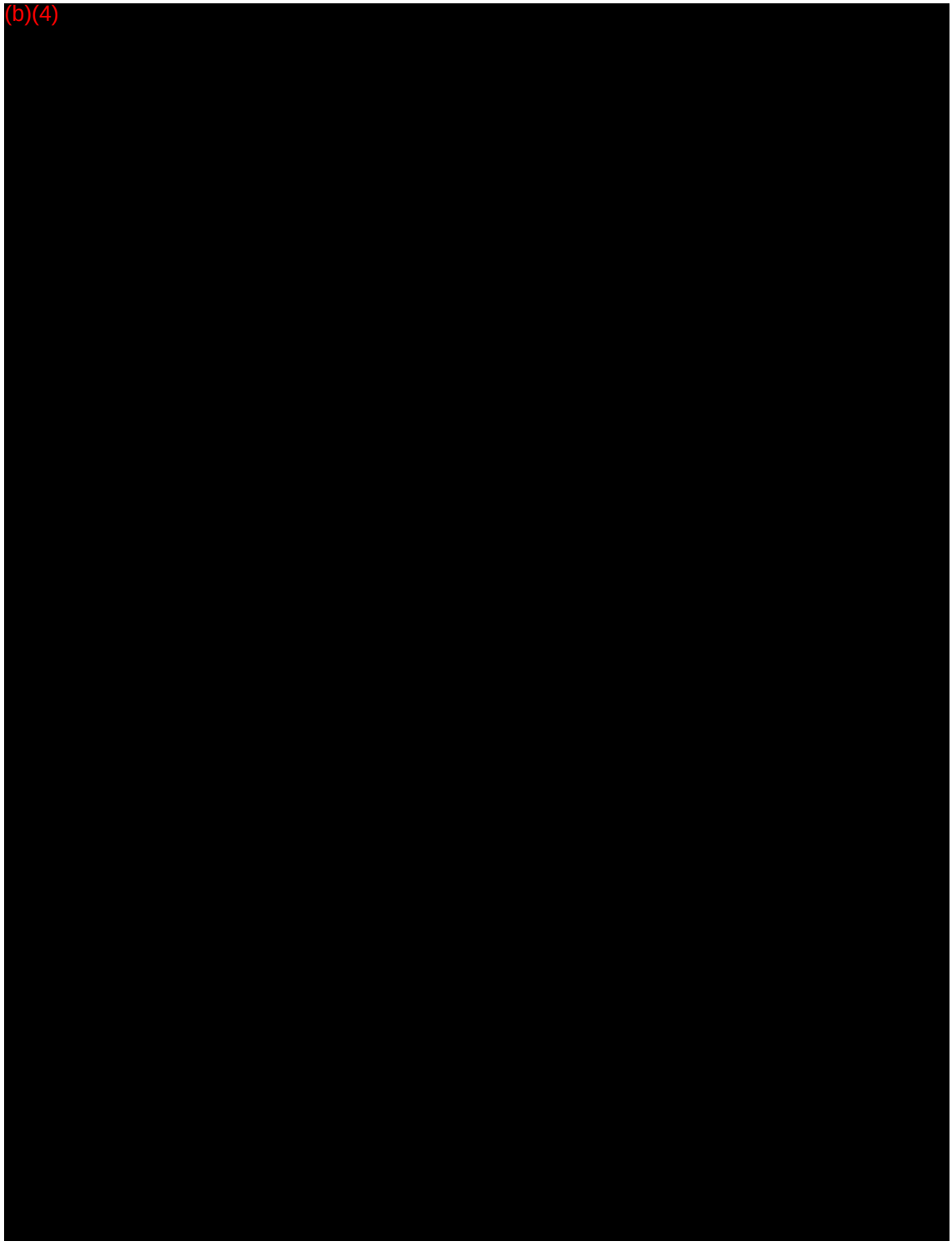
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Results,
Continued

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Results,
Continued

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Results,
Continued

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER FLEXIBILITY AND KINK TEST – *Continued*

Conclusion

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE

Purpose

To determine the number of rotations required to break joints and/or materials or to lose functional integrity of the catheter.

Materials

- EtO Sterilized TREK OTW and MINI TREK OTW

1.50 mm x 6 mm	1.50 mm x 20 mm	2.00 mm x 6 mm
2.00 mm x 30 mm	2.25 mm x 6 mm	2.25 mm x 30 mm
3.50 mm x 30 mm	4.00 mm x 6 mm	4.00 mm x 30 mm
5.00 mm x 12 mm	5.00 mm x 15 mm	

- Aged, EtO Sterilized TREK OTW and MINI TREK OTW

2.00 mm x 30 mm	5.00 mm x 15 mm

- Catheter torque test fixture
- Tortuosity fixture
- Tortuosity tubing, 40" Teflon, 0.138" ID
- Water bath, 37°C
- 0.014" guide wire
- Indeflator
- Isopropyl alcohol
- Contrast medium
- 20 cc and 60 cc syringes
- Count down timer
- Hemostats
- Flushing tool
- 3-way stopcock
- Stop watch

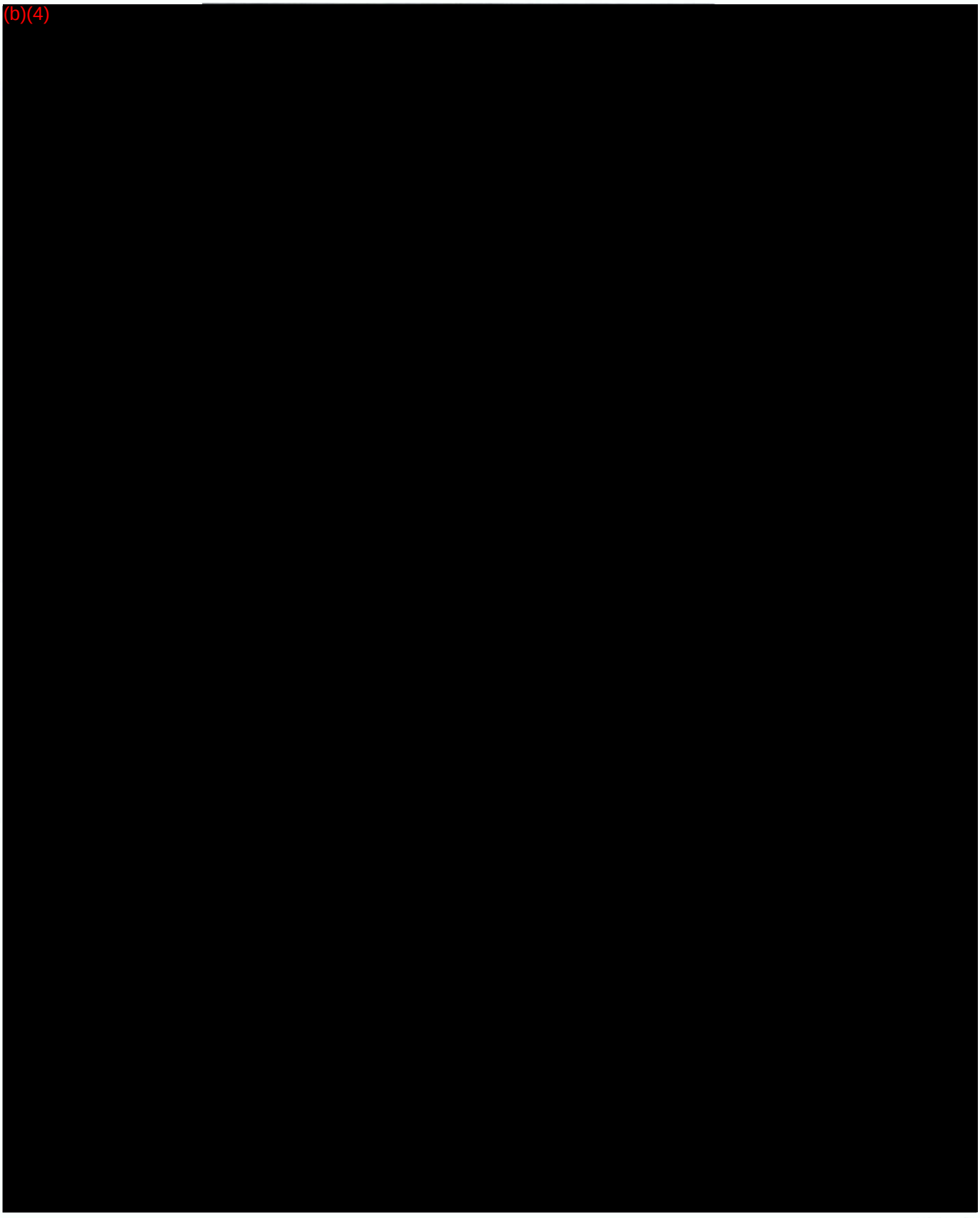
Note: A pictorial representation of the torque test fixture is provided below. During the test, tortuosity fixture is submerged in a water bath maintained at 37°C. This fixture and test method were previously included in the submission and subsequent approval for the VOYAGER® NC Coronary Dilatation Catheter 1.50 mm balloon diameter line extension (Approved February 4, 2010).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

(b)(4)



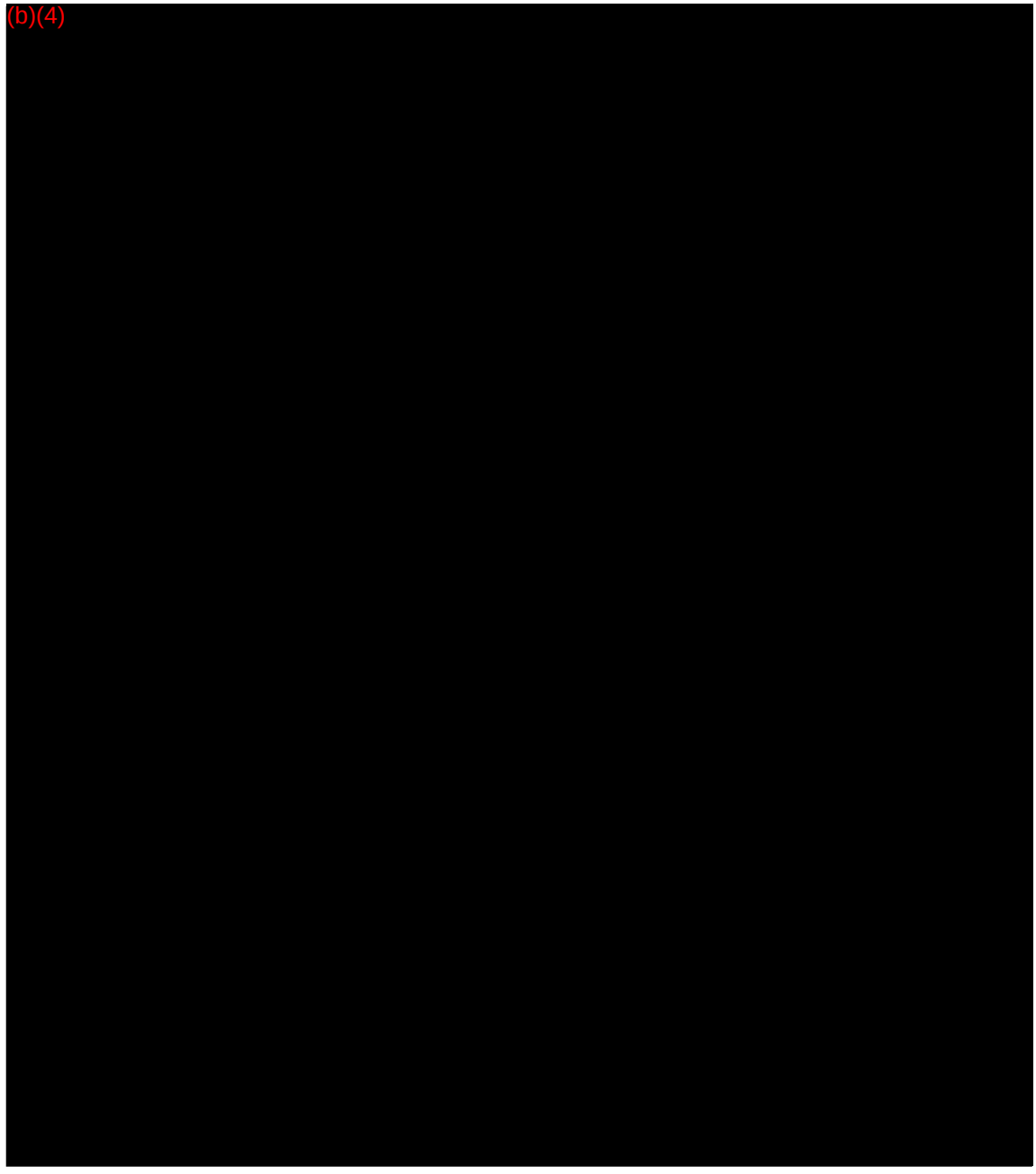
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

Procedure, Continued

(b)(4)



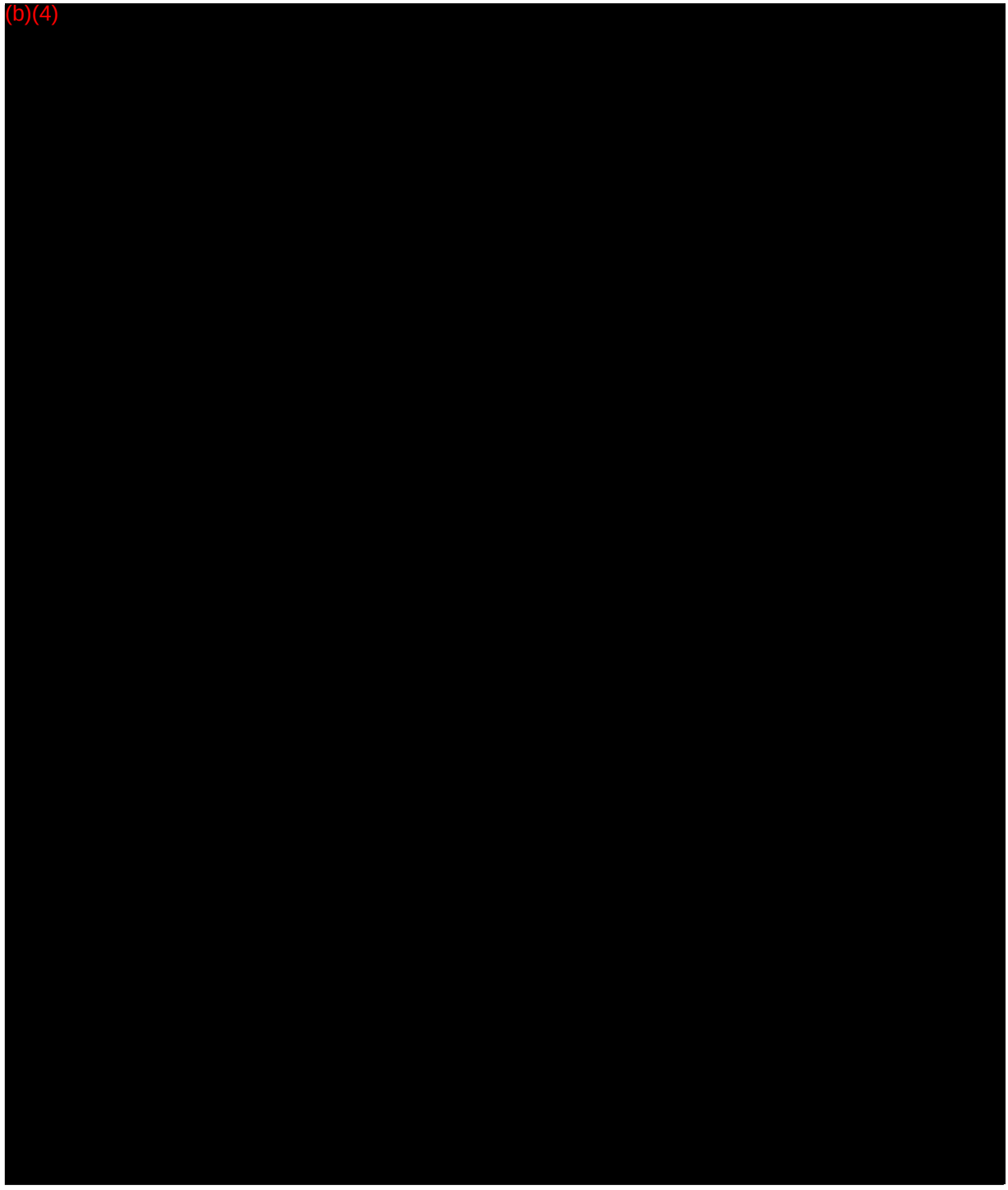
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

Results

(b)(4)



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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

Results,
Continued

(b)(4)

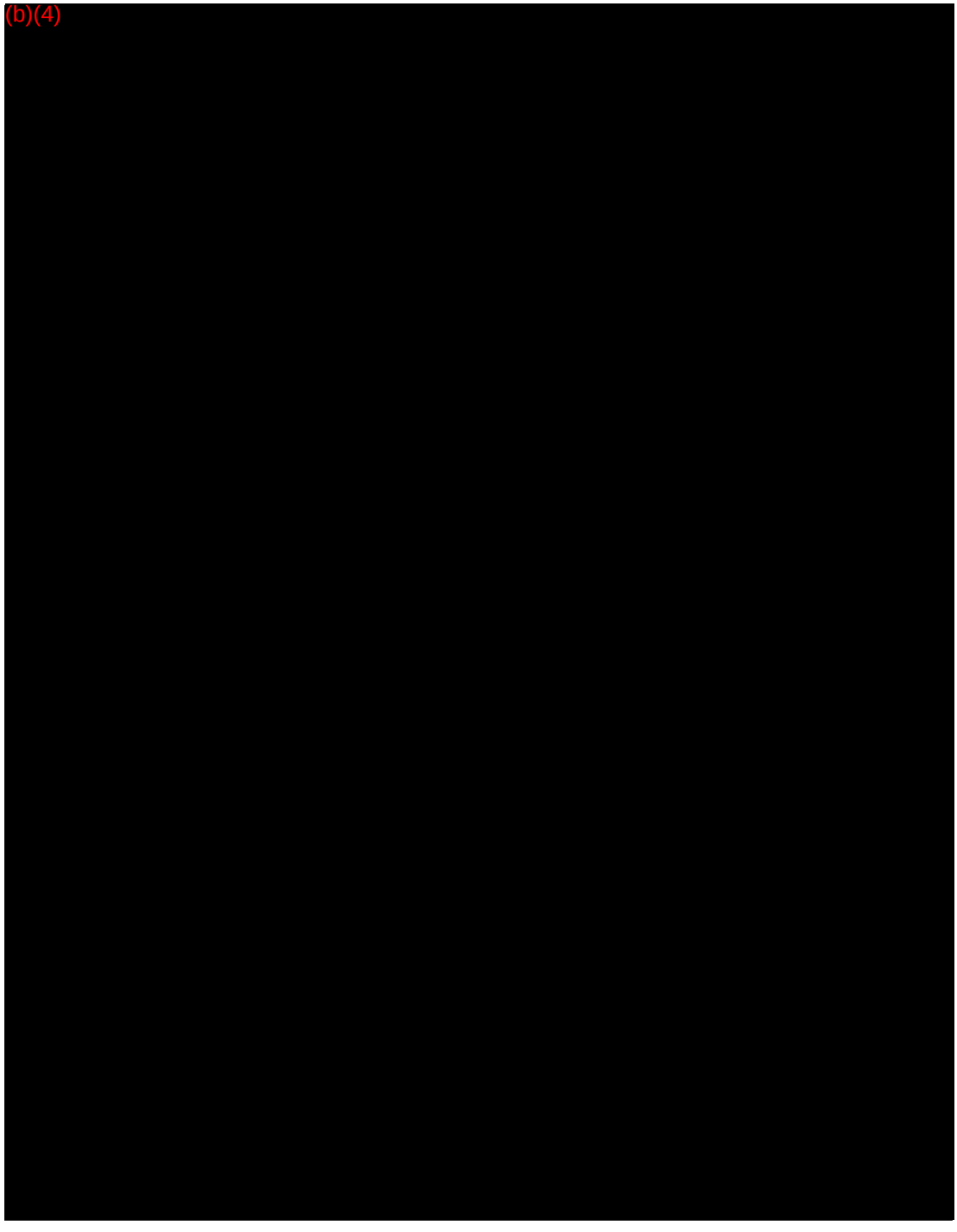
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

Results,
Continued

(b)(4)



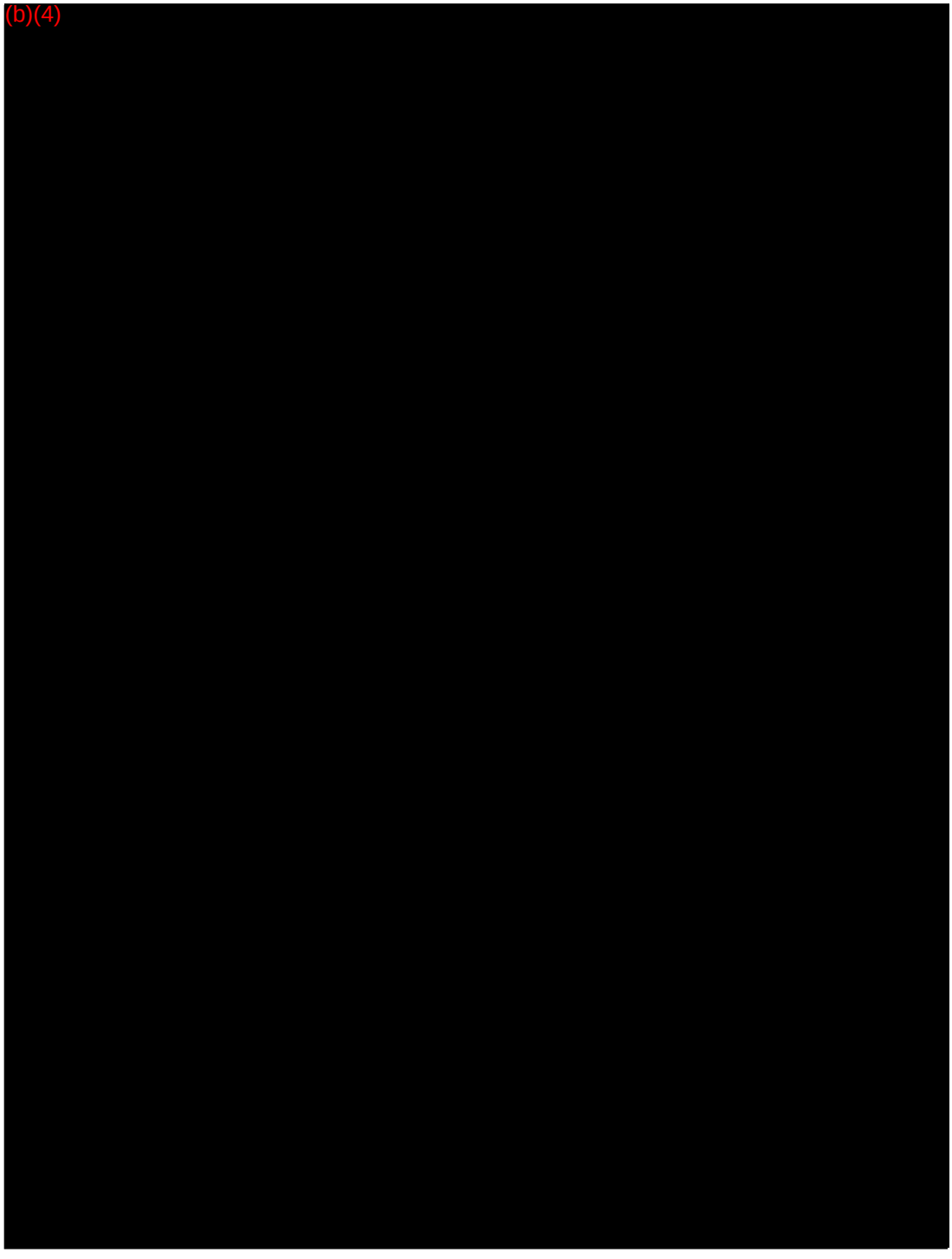
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

Results,
Continued

(b)(4)

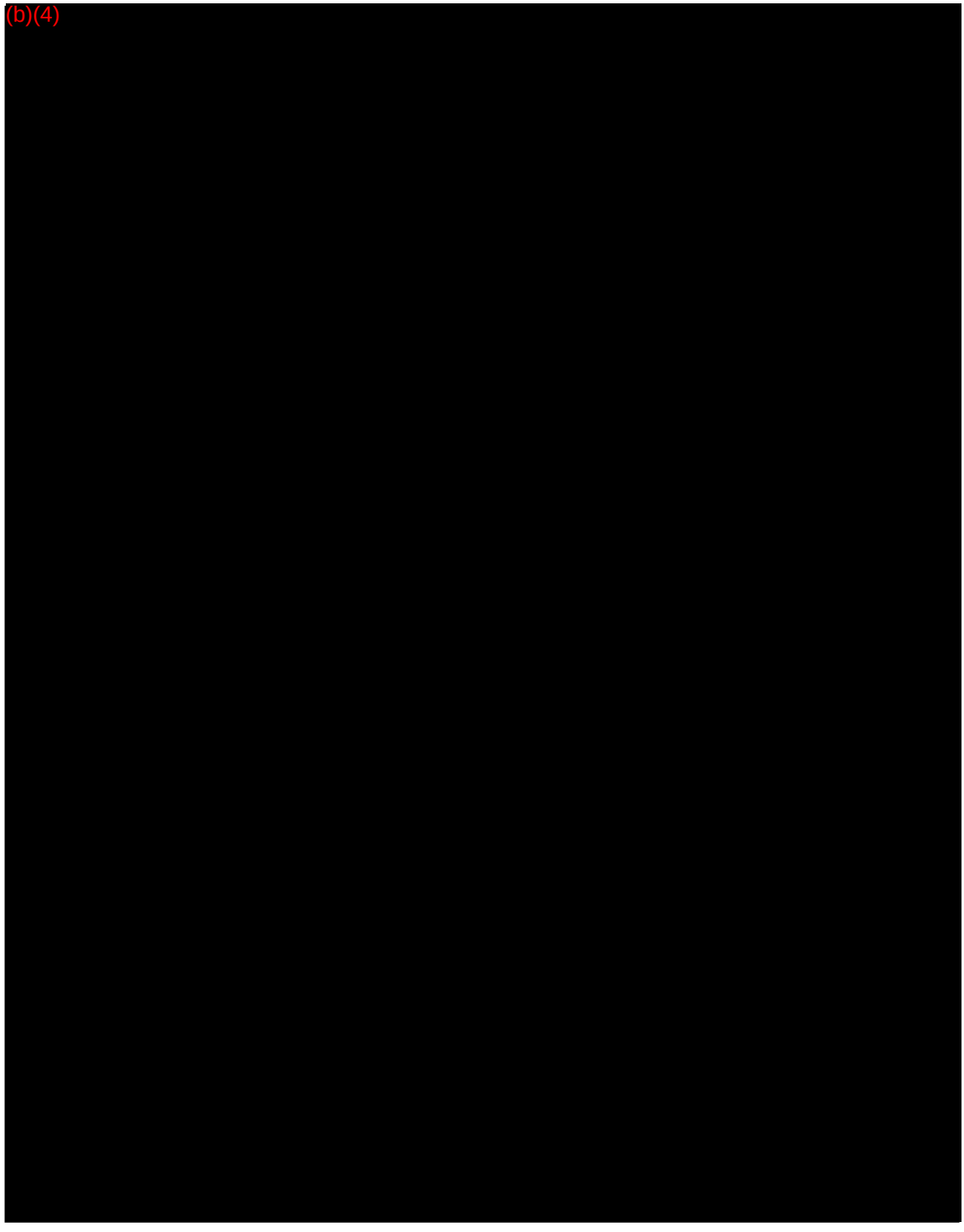


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Results,
Continued

(b)(4)



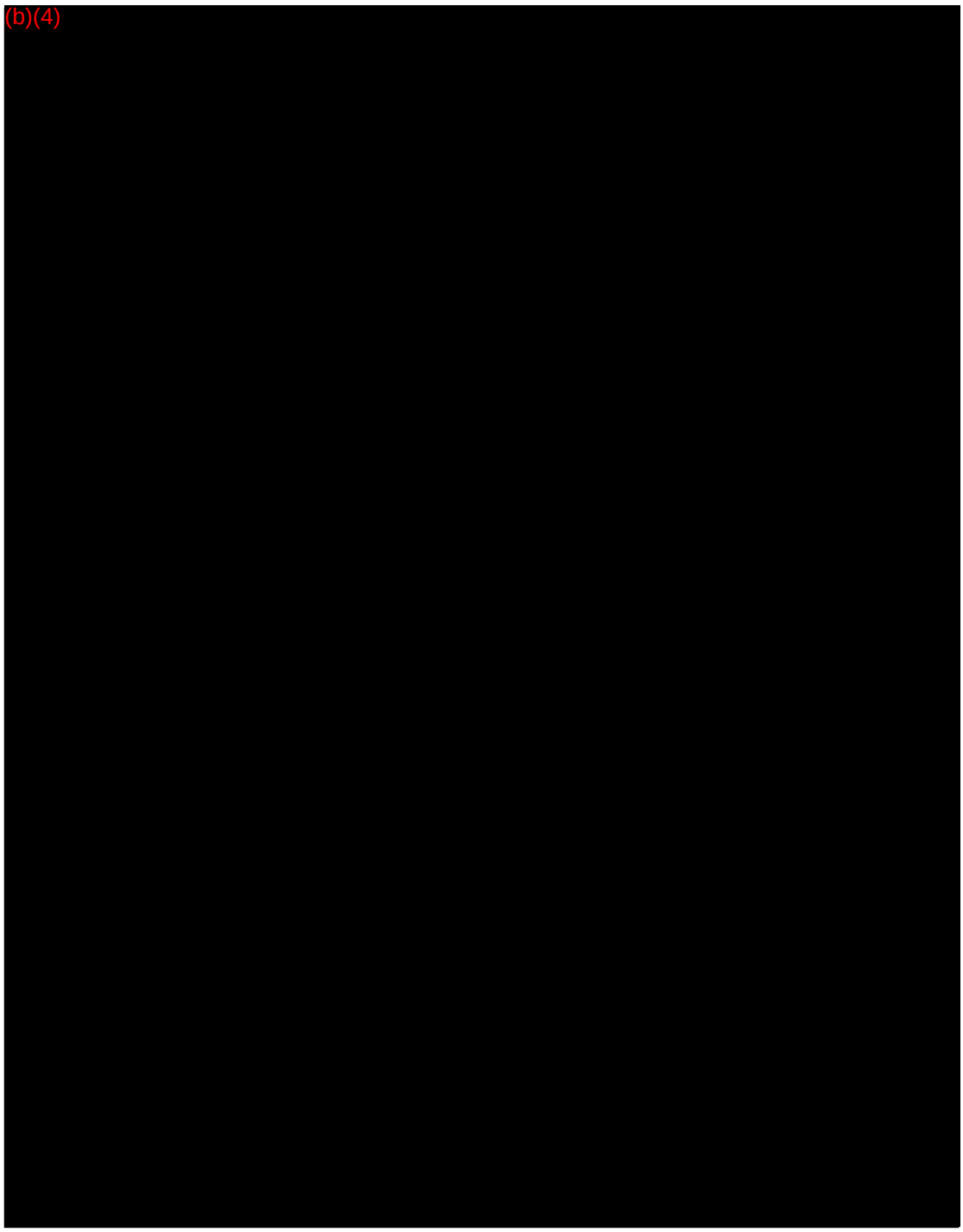
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

Results,
Continued

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CATHETER TORQUE TEST – TURNS TO FAILURE – *Continued*

Results,
Continued

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

RADIOPACITY

Purpose

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

6.5 RISK ANALYSIS

The risk analysis was performed to systematically evaluate product safety; identify hazards, their causes and the effects that each hazard has on product safety and use; and allow improvement into the design and development of the products; prevention through process controls and/or detection methods. The risk analysis for the TREK RX and MINI TREK RX Coronary Dilatation Catheters, included in P810046/S235, has been revised to include the MINI TREK OTW and TREK OTW. This revised risk assessment is provided in **Appendix A20-II**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SECTION 7

SOLE INVESTIGATOR

This section is not applicable and is, therefore, intentionally left blank

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SECTION 8

BIBLIOGRAPHY

The bibliography for coronary dilatation catheters approved under P810046 was updated in January 2010 with annual report P810046/R039. Further bibliography updates will be included in the next annual report covering January 1, 2010 through December 31, 2010.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SECTION 9

DEVICE SAMPLES

Sample catheters can be provided at the request of the Food and Drug Administration.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

SECTION 10

LABELING

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are packaged and labeled with the following items:

- Product Label (Pouch and Box/Carton)
- Compliance Chart Card
- Instructions for Use (IFU) Booklet

The following pages include sample product labels, compliance chart cards, and IFU. Labeled balloon length, balloon diameters, model numbers, and balloon compliance information are modified accordingly for each size.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Sample Pouch and Box/Carton Labels: TREK™ RX and MINI TREK™ Coronary Dilatation Catheters

741

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

MINI TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

MINI TREK
Coronary Dilatation Catheter

1.50 **6**

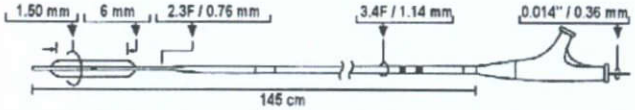
REF 1012402-06 LOT 00902T1 2012-08

(01)08717648153761(17)120831(10)00902T1(91)3912

REF 1012402-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter, Cathéter de dilatation coronaire , Catéter para dilatación coronaria Catetere per dilatazione coronarica Cateter para Dilatação Coronária Koronar dilatationskateter, Coronaire dilatatiekatheter Koronardilatationskateter, Καθετήρας διαστολής στεφανιαίας αρτηρίας, 冠動脈拡張用カテーテル Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter Koronární dilatační katetr; Koroner Dilatasyon Kateteri, Koronardilatasjonskateter Коронарен дилатационен катетър, Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelvaltimon laajennuskatetri

ATM	kPa	
2	200	1.34 mm
3	300	1.36 mm
4	400	1.38 mm
5	500	1.40 mm
6	600	1.43 mm
7	700	1.45 mm
8 (NOM)	800	1.47 mm
9	900	1.49 mm
10	1000	1.51 mm
11	1100	1.52 mm
12	1200	1.54 mm
13	1300	1.55 mm
14 (RBP)	1400	1.56 mm
15	1500	1.57 mm
16	1600	1.59 mm
17	1700	1.60 mm



Consult instructions for use. Gebrauchsanweisung lesen Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita.

1 STERILE EO Rx ONLY 2

MINI TREK is a trademark of the Abbott Group of Companies.

WPL2076076-06 (6/25/10)

Abbott Vascular
Santa Clara CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8874
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular
International BVBA
1831 Diegem BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075204 (4/29/10)

MINI TREK
1.50 mm x 6 mm
145 cm
REF 1012402-06
LOT 00902T1 OTW

MINI TREK
1.50 mm x 6 mm
145 cm
REF 1012402-06
LOT 00902T1 OTW

MINI TREK 1.50 mm x 6 mm, 145 cm

OTW

(01) 0 8717648 15376 1 REF 1012402-06

(17) 120831 (10) 00902T1 (91) 3912

LOT 00902T1 2010-09 2012-08

10 - 3

742

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

MINI TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

MINI TREK Coronary Dilatation Catheter

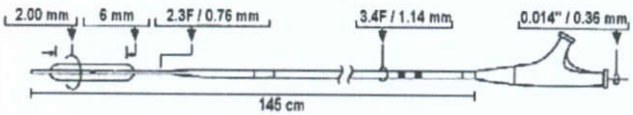
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REF 1012403-06 LOT 00902T1 2012-08

(01)08717648153815(17)120831(10)00902T1(91)3901

REF 1012403-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter; Cathéter de dilatation coronaire; Catéter para dilatación coronaria; Catetere per dilatazione coronarica; Cateter para Dilatação Coronária; Koronar dilatationskateter; Coronaire dilatatiekatheter; Koronardilatationskateter; Καθετήρας διαστολής στεφανιαίας αρτηρίας; 冠動脈拡張用カテーテル; Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter; Koronární dilatační katetr; Koroner Dilatasyon Kateteri; Koronardilatasjonskateter; Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelvaltimon laajennuskatetri



Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita.

1 STERILE EO Rx ONLY 2 PACK

MINI TREK is a trademark of the Abbott Group of Companies

ATM	kPa	
2	200	1.69 mm
3	300	1.80 mm
4	400	1.85 mm
5	500	1.90 mm
6	600	1.94 mm
7	700	1.98 mm
8 (NOM)	800	2.01 mm
9	900	2.03 mm
10	1000	2.07 mm
11	1100	2.09 mm
12	1200	2.12 mm
13	1300	2.14 mm
14 (RBP)	1400	2.17 mm
15	1500	2.19 mm
16	1600	2.21 mm
17	1700	2.24 mm

WPL2076076-11 (6/25/10)

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-6874
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular International BVBA
1831 Diegem, BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075204 (4/29/10)

MINI TREK
2.00 mm x 6 mm
145 cm
REF 1012403-06
LOT 00902T1 OTW

MINI TREK
2.00 mm x 6 mm
145 cm
REF 1012403-06
LOT 00902T1 OTW

MINI TREK 2.00 mm x 6 mm, 145 cm OTW

(01) 0 8717648 15381 5 REF 1012403-06

(17) 120831 (10) 00902T1 (91) 3901

LOT 00902T1 2010-09 2012-08

10 - 4

743

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK Coronary Dilatation Catheter

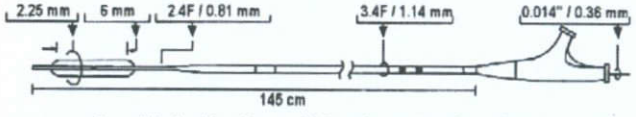
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REF 1012404-06 LOT 00902T1 2012-08

(01)08717648153884(17)120831(10)00902T1(91)3901

REF 1012404-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter. Cathéter de dilatation coronaire. Catéter para dilatación coronaria. Catetere per dilatazione coronarica. Cateter para Dilatação Coronária. Koronar dilatationskateter. Coronaire dilatatiekatheter. Koronardilatationskateter. Καθετήρας διαστολής στεφανιαίας αρτηρίας. 冠動脈拡張用カテーテル. Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter. Koronární dilatační katetr; Koroner Dilatasyon Kateteri. Koronardilatasjonskateter. Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий. Sepeltäytimen laajennuskatetri



ATM	kPa	
2	200	1.87 mm
3	300	1.95 mm
4	400	2.00 mm
5	500	2.06 mm
6	600	2.12 mm
7	700	2.17 mm
8 (NOM)	800	2.21 mm
9	900	2.25 mm
10	1000	2.28 mm
11	1100	2.31 mm
12	1200	2.33 mm
13	1300	2.35 mm
14 (RBP)	1400	2.37 mm
15	1500	2.39 mm
16	1600	2.41 mm
17	1700	2.43 mm

WPL2076076-18 (6/25/10)

Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita.

1 STERILE EO Rx ONLY 2

TREK is a trademark of the Abbott Group of Companies

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8874
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular
International BVBA
1831 Diegem BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
2.25 mm x 6 mm
145 cm
REF 1012404-06
LOT 00902T1 OTW

TREK
2.25 mm x 6 mm
145 cm
REF 1012404-06
LOT 00902T1 OTW

TREK 2.25 mm x 6 mm, 145 cm

OTW

(01) 0 8717648 15388 4 REF 1012404-06

(17) 120831 (10) 00902T1 (91) 3901

LOT 00902T1 2010-09 2012-08

10 - 5 744

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK Coronary Dilatation Catheter

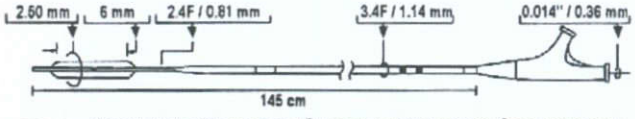
2.50 **6**

REF 1012405-06 LOT 00902T1 2012-08

(01)08717648153952(17)120831(10)00902T1(91)3901

REF 1012405-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter, Cathéter de dilatation coronaire, Catéter para dilatación coronaria, Catetere per dilatazione coronarica, Cateter para Dilatação Coronária, Koronar dilatationskateter, Coronaire dilatatiekatheter, Koronardilatationskateter, Καθετήρας διαστολής στεφανιαίας αρτηρίας 冠動脈拡張用カテーテル, Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter Koronární dilatační katetr, Koroner Dilatasyon Kateteri, Koronardilatasjonskateter, Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelvaltimon laajennuskatetri



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1 STERILE EO Rx ONLY 2

TREK is a trademark of the Abbott Group of Companies.

ATM	kPa	
2	200	2.15 mm
3	300	2.20 mm
4	400	2.27 mm
5	500	2.34 mm
6	600	2.40 mm
7	700	2.45 mm
8 (NOM)	800	2.51 mm
9	900	2.55 mm
10	1000	2.58 mm
11	1100	2.60 mm
12	1200	2.62 mm
13	1300	2.64 mm
14 (RBP)	1400	2.67 mm
15	1500	2.69 mm
16	1600	2.71 mm
17	1700	2.73 mm

WPL2076076-25 (6/25/10)

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8874
Outside USA TEL (951) 914-4668
Outside USA FAX (951) 914-2531

Abbott Vascular International BVBA
1831 Diegem, BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
2.50 mm x 6 mm
145 cm
REF 1012405-06
LOT 00902T1 OTW

TREK
2.50 mm x 6 mm
145 cm
REF 1012405-06
LOT 00902T1 OTW

TREK 2.50 mm x 6 mm, 145 cm OTW

(01) 0 8717648 15395 2 REF 1012405-06

(17) 120831 (10) 00902T1 (91) 3901

LOT 00902T1 2010-09 2012-08

745

10 - 6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK
Coronary Dilatation Catheter

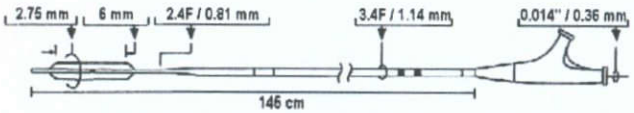
2.75 **6**

REF 1012406-06 LOT 00902T1 2012-08

(01)08717648154027(17)120831(10)00902T1(91)3901

REF 1012406-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter. Cathéter de dilatation coronaire . Catéter para dilatación coronaria, Catetere per dilatazione coronarica Cateter para Dilatação Coronária. Koronar dilatationskateter. Coronaire dilatatiekatheter. Koronardilatationskateter. Καθετήρας διαστολής στεφανιαίας αρτηρίας 冠動脈拡張用カテーテル. Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter Koronární dilatační katetr; Koroner Dilatasyon Kateteri, Koronardilatasjonskateter. Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий. Sepelvaltimon laajennuskatetri



Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita.

1 STERILE EO Rx ONLY

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ATM	kPa	
2	200	2.16 mm
3	300	2.35 mm
4	400	2.41 mm
5	500	2.49 mm
6	600	2.56 mm
7	700	2.63 mm
8 (NOM)	800	2.70 mm
9	900	2.75 mm
10	1000	2.80 mm
11	1100	2.83 mm
12	1200	2.86 mm
13	1300	2.88 mm
14 (RBP)	1400	2.91 mm
15	1500	2.92 mm
16	1600	2.96 mm
17	1700	2.99 mm

WPL2076076-32 (6/25/10)

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-6874
Outside USA TEL (951) 914-4689
Outside USA FAX (951) 914-2531

Abbott Vascular
International BVBA
1831 Diegem, BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
2.75 mm x 6 mm
145 cm
REF 1012406-06
LOT 00902T1 OTW

TREK
2.75 mm x 6 mm
145 cm
REF 1012406-06
LOT 00902T1 OTW

TREK 2.75 mm x 6 mm, 145 cm

(01) 0 8717648 15402 7 REF 1012406-06 OTW

(17) 120831 (10) 00902T1 (91) 3901

LOT 00902T1 2010-09 2012-08

10 - 7

746

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK
Coronary Dilatation Catheter

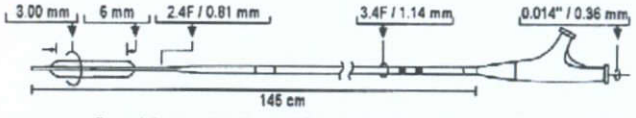
3.00 **6**

REF 1012407-06 LOT 00902T1 2012-08

(01)08717648154096(17)120831(10)00902T1(91)4812

REF 1012407-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter Cathéter de dilatation coronaire . Catéter para dilatación coronaria Catetere per dilatazione coronarica Cateter para Dilatação Coronária. Koronar dilatationskateter, Coronaire dilatatiekatheter, Koronardilatationskateter Καθετήρας διαστολής στεφανιαίας αρτηρίας 冠動脈拡張用カテーテル. Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter Koronární dilatační katetr; Koroner Dilatasyon Kateteri, Koronardilatasjonskateter Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelvaltimon laajennuskatetri



Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita

1 STERILE EO Rx ONLY 2

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ATM	kPa	
2	200	2.49 mm
3	300	2.56 mm
4	400	2.66 mm
5	500	2.73 mm
6	600	2.81 mm
7	700	2.87 mm
8 (NOM)	800	2.93 mm
9	900	2.97 mm
10	1000	3.01 mm
11	1100	3.04 mm
12	1200	3.07 mm
13	1300	3.09 mm
14 (RBP)	1400	3.11 mm
15	1500	3.14 mm
16	1600	3.16 mm
17	1700	3.18 mm

WPL2076076-39 (6/25/10)

Abbott Vascular
Santa Clara CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8674
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular International BVBA
1831 Diegem BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
3.00 mm x 6 mm
145 cm
REF 1012407-06
LOT 00902T1 OTW

TREK
3.00 mm x 6 mm
145 cm
REF 1012407-06
LOT 00902T1 OTW

TREK 3.00 mm x 6 mm, 145 cm

OTW

(01) 0 8717648 15409 6 REF 1012407-06

(17) 120831 (10) 00902T1 (91) 4812

LOT 00902T1 2010-09 2012-08

10 - 8 747

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK Coronary Dilatation Catheter

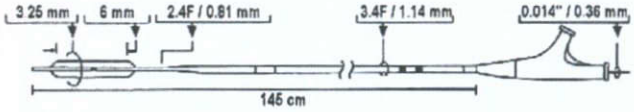
3.25 **6**

REF 1012408-06 LOT 00902T1 2012-06

(01)08717648154164(17)120831(10)00902T1(91)4801

REF 1012408-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter, Cathéter de dilatation coronaire Catéter para dilatación coronaria. Catetere per dilatazione coronarica Cateter para Dilatação Coronária. Koronar dilatationskateter. Coronaire dilatatiekatheter Koronardilatationskateter Καθετήρας διαστολής στεφανιαίος αρτηρίας 冠動脈拡張用カテーテル Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter. Koronární dilatační katetr; Koroner Dilatasyon Kateteri, Koronardilatasjonskateter Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelvaltimon laajennuskatetri



ATM	kPa	
2	200	2.91 mm
3	300	2.98 mm
4	400	3.05 mm
5	500	3.12 mm
6	600	3.19 mm
7	700	3.25 mm
8 (NOM)	800	3.31 mm
9	900	3.36 mm
10	1000	3.39 mm
11	1100	3.42 mm
12	1200	3.45 mm
13	1300	3.48 mm
14 (RBP)	1400	3.50 mm
15	1500	3.53 mm
16	1600	3.56 mm
17	1700	3.58 mm

WPL2076076-46 (6/25/10)

Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita.

1 STERILE EO Rx ONLY 2

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Abbott Vascular
Santa Clara, CA 95054-2807 USA

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FAX (800) 601-8674
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular International BVBA
1831 Diegem, BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
3.25 mm x 6 mm
145 cm
REF 1012408-06
LOT 00902T1 OTW

TREK
3.25 mm x 6 mm
145 cm
REF 1012408-06
LOT 00902T1 OTW

TREK 3.25 mm x 6 mm, 145 cm

OTW

(01) 0 8717648 15416 4 REF 1012408-06

(17) 120831 (10) 00902T1 (91) 4801

LOT 00902T1 2010-09 2012-08

10 - 9 748

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK
Coronary Dilatation Catheter

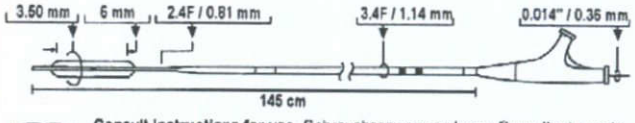
3.50 **6**

REF 1012409-06 LOT 00902T1 2012-08

(01)08717648154232(17)120831(10)00902T1(91)4801

REF 1012409-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter, Cathéter de dilatation coronaire. Catéter para dilatación coronaria. Catetere per dilatazione coronarica. Cateter para Dilatação Coronária. Koronar dilatationskateter. Coronaire dilatatiekatheter. Koronardilatationskateter. Καθετήρας διαστολής στεφανιαίας αρτηρίας. 冠動脈拡張用カテーテル. Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter. Koronární dilatační katetr; Koroner Dilatasyon Kateteri. Koronardilatasjonskateter. Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelvaltimon laajennuskatetri



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1 STERILE EO Rx ONLY 2 PYROGEN

TREK is a trademark of the Abbott Group of Companies.

ATM	kPa	
2	200	2.93 mm
3	300	3.04 mm
4	400	3.11 mm
5	500	3.20 mm
6	600	3.28 mm
7	700	3.38 mm
8 (NOM)	800	3.45 mm
9	900	3.51 mm
10	1000	3.56 mm
11	1100	3.60 mm
12	1200	3.64 mm
13	1300	3.67 mm
14 (RBP)	1400	3.70 mm
15	1500	3.73 mm
16	1600	3.75 mm
17	1700	3.78 mm

WPL2076076-53 (6/25/10)

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8874
Outside USA TEL (951) 914-4569
Outside USA FAX (951) 914-2531

Abbott Vascular International BVBA
1831 Diegem BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
3.50 mm x 6 mm
145 cm
REF 1012409-06
LOT 00902T1 OTW

TREK
3.50 mm x 6 mm
145 cm
REF 1012409-06
LOT 00902T1 OTW

TREK 3.50 mm x 6 mm, 145 cm OTW

(01) 0 8717648 15423 2 REF 1012409-06

(17) 120831 (10) 00902T1 (91) 4801

LOT 00902T1 2010-09 2012-08

749

10 - 10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK
Coronary Dilatation Catheter

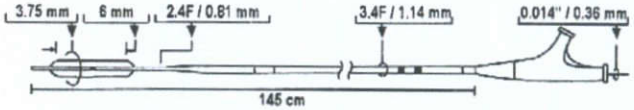
3.75 **6**

REF 1012410-06 LOT 00902T1 2012-08

(01)08717648154300(17)120831(10)00902T1(91)4801

REF 1012410-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter. Cathéter de dilatation coronaire. Catéter para dilatación coronaria. Catetere per dilatazione coronarica. Cateter para Dilatação Coronária. Koronar dilatationskateter. Coronaire dilatatiekatheter. Koronardilatationskateter. Καθετήρας διαστολής στεφανιαίας αρτηρίας. 冠動脈拡張用カテーテル. Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter. Koronární dilatační katetr; Koroner Dilatasyon Kateteri; Koronardilatasjonskateter. Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelvaltimon laajennuskatetri



Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita

1 **STERILE EO** Rx ONLY

TREK is a trademark of the Abbott Group of Companies.

ATM	kPa	
2	200	3.06 mm
3	300	3.22 mm
4	400	3.31 mm
5	500	3.41 mm
6	600	3.50 mm
7	700	3.59 mm
8 (NOM)	800	3.67 mm
9	900	3.74 mm
10	1000	3.79 mm
11	1100	3.84 mm
12	1200	3.87 mm
13	1300	3.91 mm
14 (RBP)	1400	3.94 mm
15	1500	3.99 mm
16	1600	4.02 mm
17	1700	4.05 mm

WPL2076076-60 (6/25/10)

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8874
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular
International BVBA
1831 Diegem, BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
3.75 mm x 6 mm
145 cm
REF 1012410-06
LOT 00902T1 OTW

TREK
3.75 mm x 6 mm
145 cm
REF 1012410-06
LOT 00902T1 OTW

TREK 3.75 mm x 6 mm, 145 cm

OTW

(01) 0 8717648 15430 0 REF 1012410-06

(17) 120831 (10) 00902T1 (91) 4801

LOT 00902T1 2010-09 2012-08

10 - 11 750

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK
Coronary Dilatation Catheter

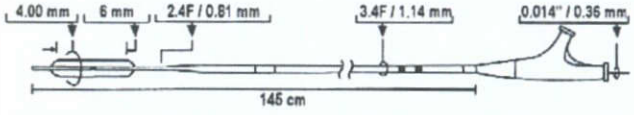
4.00 **6**

REF 1012411-06 LOT 00902T1 2012-08

(01)08717648154379(17)120831(10)00902T1(91)3901

REF 1012411-06

Coronary Dilatation Catheter; Koronar-Dilatationskatheter, Cathéter de dilatation coronaire, Catéter para dilatación coronaria, Catetere per dilatazione coronarica, Cateter para Dilatação Coronária, Koronar dilatationskateter, Coronaire dilatatiekatheter, Koronardilatationskateter, Καθετήρας διαστολής στεφανιαίας αρτηρίας, 拡張用カテーテル, Wieńcowy cewnik rozszerzający, Szívkoszorúér tágító katéter, Koronární dilatační katetr, Koroner Dilatasyon Kateteri, Koronardilatasjonskateter, Коронарен дилатационен катетър, Cateter de dilatare coronariană, Катетер для баллонной дилатации коронарных артерий, Sepelvaltimon laajennuskatetri



Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης, 取扱説明書をご参照ください。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita.

1 STERILE EO Rx ONLY 2 2

TREK is a trademark of the Abbott Group of Companies.

ATM	kPa	
2	200	3.24 mm
3	300	3.46 mm
4	400	3.56 mm
5	500	3.67 mm
6	600	3.78 mm
7	700	3.89 mm
8 (NOM)	800	3.99 mm
9	900	4.08 mm
10	1000	4.11 mm
11	1100	4.18 mm
12	1200	4.23 mm
13	1300	4.28 mm
14 (RBP)	1400	4.32 mm
15	1500	4.38 mm
16	1600	4.44 mm
17	1700	4.49 mm

WPL2076076-67 (6/25/10)

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8674
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular
International BVBA
1831 Diegem, BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
4.00 mm x 6 mm
145 cm
REF 1012411-06
LOT 00902T1 OTW

TREK
4.00 mm x 6 mm
145 cm
REF 1012411-06
LOT 00902T1 OTW

TREK 4.00 mm x 6 mm, 145 cm

OTW

(01) 0 8717648 15437 9 REF 1012411-06

(17) 120831 (10) 00902T1 (91) 3901

LOT 00902T1 2010-09 2012-08

10 - 12

751

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK Coronary Dilatation Catheter

4.50 12

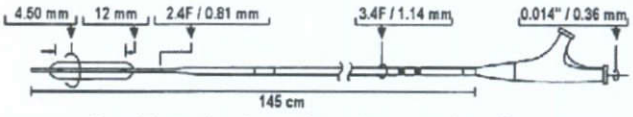
REF 1012412-12 LOT 00902T1 2012-08

(01)08717648154447(17)120831(10)00902T1(91)4801

REF 1012412-12

Coronary Dilatation Catheter: Koronar-Dilatationskatheter, Cathéter de dilatation coronaire , Catéter para dilatación coronaria Catetere per dilatazione coronarica, Cateter para Dilatação Coronária, Koronar dilatationskateter, Coronaire dilatatiekatheter, Koronardilatationskateter, **Καθετήρας διαστολής στεφανιαίας αρτηρίας**, 冠動脈拡張用カテーテル, Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter, Koronární dilatační katetr; Koroner Dilatasyon Kateteri, Koronardilatasjonskateter, Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий, Sepelvaltimon laajennuskateter

ATM	kPa	
2	200	3.69 mm
3	300	3.91 mm
4	400	4.04 mm
5	500	4.17 mm
6	600	4.29 mm
7	700	4.40 mm
8 (NOM)	800	4.49 mm
9	900	4.56 mm
10	1000	4.62 mm
11	1100	4.68 mm
12	1200	4.73 mm
13	1300	4.80 mm
14 (RBP)	1400	4.86 mm
15	1500	4.92 mm
16	1600	4.98 mm
17	1700	5.04 mm



Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso Consultare le istruzioni per l'uso Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. **Συμβουλευτείτε τις οδηγίες χρήσης**. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. **Вижте инструкциите за употреба.** Consultați instrucțiunile de utilizare **Ознакомьтесь с инструкциями по применению** Katso käyttöohjeita.

1 **STERILE EO** Rx ONLY

TREK is a trademark of the Abbott Group of Companies.

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8874
Outside USA TEL (951) 914-4669
Outside USA FAX (951) 914-2531

Abbott Vascular International BVBA
1831 Diegem BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

WPL2076076-74 (6/25/10)

PPL2075203 (4/29/10)

TREK
4.50 mm x 12 mm
145 cm
REF 1012412-12
LOT 00902T1 OTW

TREK
4.50 mm x 12 mm
145 cm
REF 1012412-12
LOT 00902T1 OTW

TREK 4.50 mm x 12 mm, 145 cm OTW

(01) 0 8717648 15444 7 REF 1012412-12

(17) 120831 (10) 00902T1 (91) 4801

LOT 00902T1 2010-09 2012-08

10 - 13 752

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Abbott

TREK

Coronary Dilatation Catheter

OTW OTW OTW OTW

TREK Coronary Dilatation Catheter

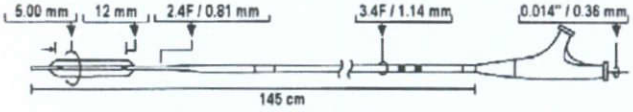
5.00 12

REF 1012413-12 LOT 00902T1 2012-08

(01)08717648154461(17)120831(10)00902T1(91)4801

REF 1012413-12

Coronary Dilatation Catheter; Koronar-Dilatationskatheter; Cathéter de dilatation coronaire; Catéter para dilatación coronaria; Catetere per dilatazione coronarica; Cateter para Dilatação Coronária; Koronar dilatationskateter; Coronaire dilatatiekatheter; Koronardilatationskateter; Καθετήρας διαστολής στεφανιαίας αρτηρίας; 冠動脈拡張用カテーテル; Wieńcowy cewnik rozszerzający; Szívkoszorúér tágító katéter; Koronární dilatační katetr; Koroner Dilatasyon Kateteri; Koronardilatasjonskateter; Коронарен дилатационен катетър; Cateter de dilatare coronariană; Катетер для баллонной дилатации коронарных артерий; Sepelivaltimon laajennuskatetri



Consult instructions for use. Gebrauchsanweisung lesen. Consulter le mode d'emploi. Consultar las instrucciones de uso. Consultare le istruzioni per l'uso. Consultar as instruções de utilização. Se bruksanvisningen. Raadpleeg gebruiksaanwijzing. Læs brugsanvisningen. Συμβουλευτείτε τις οδηγίες χρήσης. 取扱説明書をご参照下さい。Zapoznać się z instrukcją obsługi. Lásd a használati utasítást. Viz návod k použití. Kullanım talimatlarına bakın. Les bruksanvisningen. Вижте инструкциите за употреба. Consultați instrucțiunile de utilizare. Ознакомьтесь с инструкциями по применению. Katso käyttöohjeita.

1 STERILE EO Rx ONLY

TREK is a trademark of the Abbott Group of Companies.

ATM	kPa	
2	200	4.10 mm
3	300	4.28 mm
4	400	4.43 mm
5	500	4.59 mm
6	600	4.73 mm
7	700	4.86 mm
8 (NOM)	800	4.98 mm
9	900	5.05 mm
10	1000	5.13 mm
11	1100	5.20 mm
12	1200	5.25 mm
13	1300	5.31 mm
14 (RBP)	1400	5.36 mm
15	1500	5.41 mm
16	1600	5.50 mm
17	1700	5.56 mm

WPL2076076-76 (6/25/10)

Abbott Vascular
Santa Clara, CA 95054-2807 USA

TEL (800) 227-9902
FAX (800) 601-8874
Outside USA TEL (951) 914-4660
Outside USA FAX (951) 914-2531

Abbott Vascular International BVBA
1831 Diegem, BELGIUM
TEL + 32 2 714 14 11
FAX + 32 2 714 14 12

CE 0086

PPL2075203 (4/29/10)

TREK
5.00 mm x 12 mm
145 cm
REF 1012413-12
LOT 00902T1 OTW

TREK
5.00 mm x 12 mm
145 cm
REF 1012413-12
LOT 00902T1 OTW

TREK 5.00 mm x 12 mm, 145 cm OTW

(01) 0 8717648 15446 1 REF 1012413-12

(17) 120831 (10) 00902T1 (91) 4801

LOT 00902T1 2010-09 2012-08

10 - 14 753

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Balloon Compliance Chart Cards

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

MINI TREK
1.50 mm

ATM	kPa	
2	200	1.34 mm
3	300	1.36 mm
4	400	1.38 mm
5	500	1.40 mm
6	600	1.43 mm
7	700	1.45 mm
8 (NOM)	800	1.47 mm
9	900	1.49 mm
10	1000	1.51 mm
11	1100	1.52 mm
12	1200	1.54 mm
13	1300	1.55 mm
14 (RBP)	1400	1.56 mm
15	1500	1.57 mm
16	1600	1.59 mm
17	1700	1.60 mm

WPL2074456–02 (3/15/10)

STERILE EO

Abbott

10 - 16

755

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

MINI TREK
2.00 mm

ATM	kPa	⟷
2	200	1.69 mm
3	300	1.80 mm
4	400	1.85 mm
5	500	1.90 mm
6	600	1.94 mm
7	700	1.98 mm
8 (NOM)	800	2.01 mm
9	900	2.03 mm
10	1000	2.07 mm
11	1100	2.09 mm
12	1200	2.12 mm
13	1300	2.14 mm
14 (RBP)	1400	2.17 mm
15	1500	2.19 mm
16	1600	2.21 mm
17	1700	2.24 mm

WPL2074456 – 03 (3/15/10)

STERILE | EO

Abbott

10 - 17 756

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
2.25 mm

ATM	kPa	⊖
2	200	1.87 mm
3	300	1.95 mm
4	400	2.00 mm
5	500	2.06 mm
6	600	2.12 mm
7	700	2.17 mm
8 (NOM)	800	2.21 mm
9	900	2.25 mm
10	1000	2.28 mm
11	1100	2.31 mm
12	1200	2.33 mm
13	1300	2.35 mm
14 (RBP)	1400	2.37 mm
15	1500	2.39 mm
16	1600	2.41 mm
17	1700	2.43 mm

WPL2074456 – 04 (3/15/10)

STERILE | EO

Abbott

10 - 18 757

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
2.50 mm

ATM	kPa	
2	200	2.15 mm
3	300	2.20 mm
4	400	2.27 mm
5	500	2.34 mm
6	600	2.40 mm
7	700	2.45 mm
8 (NOM)	800	2.51 mm
9	900	2.55 mm
10	1000	2.58 mm
11	1100	2.60 mm
12	1200	2.62 mm
13	1300	2.64 mm
14 (RBP)	1400	2.67 mm
15	1500	2.69 mm
16	1600	2.71 mm
17	1700	2.73 mm

WPL2074456 – 05 (3/15/10)

STERILE | EO

Abbott

10 - 19 758

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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TREK
2.75 mm

ATM	kPa	→ ○ ←
2	200	2.16 mm
3	300	2.35 mm
4	400	2.41 mm
5	500	2.49 mm
6	600	2.56 mm
7	700	2.63 mm
8 (NOM)	800	2.70 mm
9	900	2.75 mm
10	1000	2.80 mm
11	1100	2.83 mm
12	1200	2.86 mm
13	1300	2.88 mm
14 (RBP)	1400	2.91 mm
15	1500	2.92 mm
16	1600	2.96 mm
17	1700	2.99 mm

WPL2074456 – 06 (3/15/10)

STERILE | EO

Abbott

10 - 20 759

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
3.00 mm

ATM	kPa	
2	200	2.49 mm
3	300	2.56 mm
4	400	2.66 mm
5	500	2.73 mm
6	600	2.81 mm
7	700	2.87 mm
8 (NOM)	800	2.93 mm
9	900	2.97 mm
10	1000	3.01 mm
11	1100	3.04 mm
12	1200	3.07 mm
13	1300	3.09 mm
14 (RBP)	1400	3.11 mm
15	1500	3.14 mm
16	1600	3.16 mm
17	1700	3.18 mm

WPL2074456 – 07 (3/15/10)



STERILE | EO

Abbott

10 - 21

760

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
3.25 mm

ATM	kPa	⟶○⟵
2	200	2.91 mm
3	300	2.98 mm
4	400	3.05 mm
5	500	3.12 mm
6	600	3.19 mm
7	700	3.25 mm
8 (NOM)	800	3.31 mm
9	900	3.36 mm
10	1000	3.39 mm
11	1100	3.42 mm
12	1200	3.45 mm
13	1300	3.48 mm
14 (RBP)	1400	3.50 mm
15	1500	3.53 mm
16	1600	3.56 mm
17	1700	3.58 mm

WPL2074456 – 08 (3/15/10)

STERILE | EO

Abbott

10 - 22 761

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
3.50 mm

ATM	kPa	⊖
2	200	2.93 mm
3	300	3.04 mm
4	400	3.11 mm
5	500	3.20 mm
6	600	3.28 mm
7	700	3.38 mm
8 (NOM)	800	3.45 mm
9	900	3.51 mm
10	1000	3.56 mm
11	1100	3.60 mm
12	1200	3.64 mm
13	1300	3.67 mm
14 (RBP)	1400	3.70 mm
15	1500	3.73 mm
16	1600	3.75 mm
17	1700	3.78 mm

WPL2074456 – 09 (3/15/10)

STERILE | EO

Abbott

10 - 23 762

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
3.75 mm

ATM	kPa	⟷
2	200	3.06 mm
3	300	3.22 mm
4	400	3.31 mm
5	500	3.41 mm
6	600	3.50 mm
7	700	3.59 mm
8 (NOM)	800	3.67 mm
9	900	3.74 mm
10	1000	3.79 mm
11	1100	3.84 mm
12	1200	3.87 mm
13	1300	3.91 mm
14 (RBP)	1400	3.94 mm
15	1500	3.99 mm
16	1600	4.02 mm
17	1700	4.05 mm

WPL2074456 – 10 (3/15/10)

STERILE EO

Abbott

10 - 24 763

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
4.00 mm

ATM	kPa	⊖
2	200	3.24 mm
3	300	3.46 mm
4	400	3.56 mm
5	500	3.67 mm
6	600	3.78 mm
7	700	3.89 mm
8 (NOM)	800	3.99 mm
9	900	4.06 mm
10	1000	4.11 mm
11	1100	4.18 mm
12	1200	4.23 mm
13	1300	4.28 mm
14 (RBP)	1400	4.32 mm
15	1500	4.38 mm
16	1600	4.44 mm
17	1700	4.49 mm

WPL2074456 – 11 (3/15/10)

STERILE EO

Abbott

10 - 25 764

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TREK
4.50 mm

ATM	kPa	⟶○⟵
2	200	3.69 mm
3	300	3.91 mm
4	400	4.04 mm
5	500	4.17 mm
6	600	4.29 mm
7	700	4.40 mm
8 (NOM)	800	4.49 mm
9	900	4.56 mm
10	1000	4.62 mm
11	1100	4.68 mm
12	1200	4.73 mm
13	1300	4.80 mm
14 (RBP)	1400	4.86 mm
15	1500	4.92 mm
16	1600	4.98 mm
17	1700	5.04 mm

WPL2074456 – 12 (3/15/10)

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10 - 26 765

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TREK
5.00 mm

ATM	kPa	
2	200	4.10 mm
3	300	4.28 mm
4	400	4.43 mm
5	500	4.59 mm
6	600	4.73 mm
7	700	4.86 mm
8 (NOM)	800	4.98 mm
9	900	5.05 mm
10	1000	5.13 mm
11	1100	5.20 mm
12	1200	5.25 mm
13	1300	5.31 mm
14 (RBP)	1400	5.36 mm
15	1500	5.41 mm
16	1600	5.50 mm
17	1700	5.56 mm

WPL2074456 – 13 (3/15/10)

STERILE EO

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SAMPLE INSTRUCTIONS FOR USE (IFU)
TREK™ OTW and MINI TREK™ OTW Coronary Dilatation Catheter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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TREK OTW and MINI TREK OTW Coronary Dilatation Catheter

℞ ONLY

CE 0086

CAUTION

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DESCRIPTION

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is a two-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon with contrast medium. The second lumen permits the use of a guide wire to facilitate advancement of the dilatation catheter to and through the stenosis to be dilated, and the injection of contrast and / or medication through the distal tip. The dilatation catheter is coated with HYDROCOAT hydrophilic coating that is activated when wet.

This device has several markers. The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure. The proximal shaft has proximal markers that aid in gauging dilatation catheter position relative to the guiding catheter tip (marker located closest to the dilatation catheter adapter is for femoral guiding catheters and the other marker is for brachial guiding catheters).

The two-arm adapter on the proximal end of the dilatation catheter provides access to the inflation lumen and the guide wire lumen. The side arm connects with the inflation lumen and has a Luer-lock fitting for connecting the dilatation catheter to an inflation device. The central arm connects with the guide wire lumen, which allows for free movement of the inserted guide wire.

HOW SUPPLIED

Sterile – This device is sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.

This single use device cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and / or chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to contamination due to narrow gaps and / or spaces and diminished safety and / or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) TREK OTW or MINI TREK OTW Coronary Dilatation Catheter, one (1) protective sheath, and one (1) compliance card

Storage – Store in a dry, dark, cool place.

INDICATIONS

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is indicated for:

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- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion
- Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction
- Balloon dilatation of a stent after implantation (balloon models 2.00 mm – 5.00 mm only)

CONTRAINDICATIONS

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is not intended to be used to treat patients with:

- An unprotected left main coronary artery
- A coronary artery spasm in the absence of a significant stenosis

WARNINGS

This device is intended for one time use only. DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent overpressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of resistance before proceeding.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked; this may result in the shaft breaking. Instead, prepare a new catheter.

Do not torque the catheter more than one (1) full turn.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60 – 85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.

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In the event of catheter damage / separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

PRECAUTIONS

Note the "Use by" date specified on the package.

Inspect all product prior to use. Do not use if the package is open or damaged.

Prior to angioplasty, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time as determined by the physician after the procedure.

If the surface of the TREK OTW or MINI TREK OTW Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the TREK OTW or MINI TREK OTW Coronary Dilatation Catheter into the coil dispenser after procedural use.

This device should be used only by physicians experienced in angiography and PTCA and / or percutaneous transluminal angioplasty.

ADVERSE EVENTS

Possible adverse effects include, but are not limited to, the following:

- Acute myocardial infarction
- Arrhythmias, including ventricular fibrillation
- Arteriovenous fistula
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture or injury
- Death
- Drug reactions, allergic reaction to contrast medium
- Embolism
- Hemorrhage or hematoma
- Hypo / hypertension
- Infection
- Restenosis of the dilated vessel
- Total occlusion of the coronary artery or bypass graft
- Unstable angina

CLINICAL AND LABORATORY RESULTS

To evaluate the safety and effectiveness of direct PTCA as a treatment for patients with ST-segment elevation acute myocardial infarction, ACS conducted a multicenter, prospective, randomized clinical trial using primarily ACS coronary dilatation catheters. The GUSTO II Direct PTCA Substudy (GUSTO IIb) evaluated treatment of patients presenting within 12 hours of ST-segment elevation myocardial infarction with direct PTCA or accelerated recombinant tissue plasminogen activator (t-PA). The primary hypothesis was that for patients with suspected acute myocardial infarction, with ST-segment elevation, direct PTCA would result in a lower rate of 30-day mortality, nonfatal reinfarction, and nonfatal disabling stroke when compared with thrombolytic therapy.

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A total of 1138 patients were enrolled in this trial at 60 centers in 9 countries from North America, Europe, and Australia over a period of 17 months. Investigator selection criteria included those physicians who had significant experience performing primary angioplasty for patients with acute myocardial infarctions, who fulfilled the 1993 ACC volume criteria of at least 50 to 75 cases of angioplasty per year. Investigational institutions were required to have performed at least 200 angioplasties per year and have a 24-hour on call team with an established system for operating room back-up. Five hundred sixty-five patients were assigned to primary angioplasty and 573 to accelerated recombinant tissue plasminogen activator (t-PA). At initial enrollment, the first 1012 patients were also randomized in a factorial design, to intravenous heparin or intravenous hirudin, as part of the GUSTO II trial. Thereafter, all patients received intravenous heparin. At enrollment, patients were given chewable aspirin (160 mg was recommended) followed by a daily dose of 80 to 325 mg. Patients received standard medical care post assigned treatment. Other testing and adjunctive therapies were left up to the discretion of the physician.

Of the patients randomized to t-PA, 94.6% (542/573) received t-PA, 1.6% (9/573) received streptokinase, and 1.7% (10/573) had direct angioplasty. Eighty two patients (14.4%) required emergency angiography and sixty (10.5%) required emergency PTCA. Two hundred seventy (47.3%) had elective angiography and 61 (10.7%) had elective PTCA. The in-hospital procedural characteristics for patients randomized to PTCA, were 73.3% (374/510) of the infarct arteries occluded (TIMI grade 0 or 1 flow) at initial catheterization (core lab) and 79.2% (446/563) patients received PTCA. Patency after angioplasty (TIMI grade 2 or 3 flow) was achieved in 93.1% (473/508) of patients (core lab). Twenty-two (4%) required emergency angiography and 19 (3.5%) required emergency PTCA. Nineteen (3.5%) had elective angiography, and 5 (0.9%) had elective PTCA. The mean time from arrival at the hospital to treatment for patients randomized to accelerated t-PA was 1.2 ± 0.9 hours and for the PTCA treatment group was 2.2 ± 0.9 hours.

When comparing the treatment of patients with ST-segment elevation myocardial infarction with direct PTCA to treatment with accelerated t-PA, PTCA resulted in a statistically significant lower 30-day composite endpoint rate of death, reinfarction, and nonfatal disabling stroke of 9.6% versus 13.7%, respectively, (odds ratio = 0.67, p = 0.033). Additionally, the direct PTCA group had a statistically significant lower rate of recurrent ischemia at 30 days when compared to the t-PA group 5.5% (29/526) versus 9.0% (48/532), respectively, (odds ratio = 0.59, p = 0.03). The overall stroke rate for this study was 1.6% (18/1133). The stroke rate for patients treated with direct PTCA was 1.3% (7/562) versus 1.9% (11/571) for patients treated with t-PA (odds ratio = 0.64, p value = 0.36). The accelerated t-PA treatment group had a statistically significant higher rate of intracranial hemorrhagic strokes, when compared to PTCA: 1.5% (8/571) versus 0%, respectively (odds ratio = 0.06, p = 0.005). There was a statistically significant higher overall rate of bleeding in the PTCA group versus the t-PA group: 40.3% (227/563) versus 34.2% (195/571) (odds ratio = 1.30, p = 0.03). The rate of severe or life-threatening bleeding was equivalent in both treatment groups. Seventy percent (161/227) of bleeding complications in the PTCA treatment group were related to vascular access, and 62.9% (142/227) were mild in nature.

At 180 days, there was no statistical difference in the composite rate of death, reinfarction, and nonfatal disabling stroke for accelerated t-PA versus direct PTCA, 16.8% (87/517) versus 14.7% (75/509), respectively, (odds ratio = 0.88, p = 0.36). The overall rate of re-admission to the hospital for chest pain, myocardial infarction, stroke, and repeat cardiac procedures was similar between the two groups. At one year there is no statistical difference in the rate of death for accelerated t-PA versus PTCA 10.3% (52/507) versus 9.2% (46/500), respectively (odds ratio = 0.89, p = 0.57).

Direct PTCA with ACS coronary dilatation catheters is safe and effective in eligible patients presenting within 12 hours of ST-segment elevation myocardial infarction, providing a reduced composite event rate at 30 days with an equivalent clinical outcome at 180 days and one year compared with accelerated t-PA.

Direct angioplasty, when it can be accomplished on a prompt basis by experienced physicians at centers with catheterization laboratory availability, should be considered a primary treatment option for patients with acute myocardial infarction.

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MATERIALS REQUIRED

Single Use, Sterile Items (Do not resterilize or reuse.)

- Sterile heparinized normal saline
- Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery
- Hemostatic valve(s)
- Contrast medium diluted 1:1 with normal saline
- 20 cc Luer-lock syringe (optional)
- Appropriately-sized guide wire
  (diameter not to exceed the maximum guide wire for the dilatation catheter; see product label)
- Guide wire introducer
- Guide wire torque device
- Inflation device

PREPARATION FOR USE

Inspect all product prior to use. Examine the dilatation catheter for bends, kinks, or other damage. Do not use if the package is open or damaged, or if the product is damaged.

Prepare equipment to be used following manufacturer's instructions or standard procedure.

Complete the following steps to prepare the TREK OTW or MINI TREK OTW Coronary Dilatation Catheter for use:

1. Remove the protective mandrel from the distal tip of the dilatation catheter.

2. Slide the protective sheath off the balloon.

   Note: Submerge the balloon in sterile heparinized normal saline during balloon preparation to activate the coating.

3. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.

4. Evacuate air from the balloon segment using the following procedure:

   a. Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommended contrast medium.

   b. After attaching the syringe or inflation device to the balloon inflation lumen, orient the catheter with the distal tip and the balloon pointing in a downward vertical position.

   c. Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.

   d. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.

   e. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.

   f. Slowly release the device pressure to neutral.

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g. Disconnect the 20 cc syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without introducing air into the system.

CAUTION: All air must be removed from the balloon and displaced with contrast medium (diluted 1:1 with normal saline) prior to inserting into the body (repeat steps 4a through 4g, if necessary); otherwise, complications may occur.

INSTRUCTIONS FOR USE

1. Flush and fill the guide wire lumen of the dilatation catheter with heparinized normal saline.

2. Insert a guide wire carefully into and through the lumen of the dilatation catheter via the guide wire port of the two-arm adapter using a guide wire introducer, if desired. When complete, withdraw the guide wire introducer, if used.

3. Open the hemostatic valve. Insert the dilatation catheter and guide wire assembly through the hemostatic valve into the guiding catheter. To facilitate insertion, the balloon must be fully deflated to negative pressure.

   Note: Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the catheter.

4. Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibiting movement of the dilatation catheter. This will allow continuous recording of the proximal coronary artery pressure.

   Note: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guide wire movement.

5. Advance the dilatation catheter and guide wire until the appropriate proximal marker aligns with the hemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.

6. Attach a torque device for the guide wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

   Note: The TREK OTW and MINI TREK OTW Coronary Dilatation Catheter is designed to allow the exchange of guide wires while maintaining position of the dilatation catheter in the coronary artery.

7. Advance the dilatation catheter over the guide wire and into the stenosis (or stent for post-implant dilatation). Inflate the balloon to a very low pressure (1 atm or 1 bar or 15 psi) to confirm that the balloon is correctly positioned.

   Note: When using the dual wire technique, a dual hemostatic valve should be used and care taken when introducing, torquing, and removing one or both wires to avoid entanglement. Guide wires should not be rotated more than 180 degrees in either direction during the dual wire procedure. It is recommended that one wire be completely withdrawn from the patient before removing additional equipment.

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8. Inflate the balloon (not to exceed 10 total inflations in a stent or 20 total inflations without a stent) to perform PTCA (or post-implant dilatation) per standard procedure. Maintain negative pressure on the balloon between inflations.

9. Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the hemostatic valve. Tighten the hemostatic valve.

   Note: After the deflated balloon dilatation catheter is withdrawn, *it should* be wiped clean with gauze soaked with sterile heparinized normal saline and stored, submerged in a basin of sterile heparinized normal saline. Prior to reinsertion, the balloon should be submerged in sterile heparinized normal saline to reactivate the coating.

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by the American College of Cardiology and the American Heart Association.

PATENTS AND TRADEMARKS

This product and / or its use are covered by one or more of the following United States Patents: 5,046,503; 5,137,513; 5,159,937; 5,176,661; 5,234,002; 5,242,396; 5,256,143; 5,290,230; 5,300,025; 5,316,706; 5,318,527; 5,324,259; 5,344,426; 5,346,505; 5,397,305; 5,411,476; 5,480,383; 5,496,275; 5,496,346; 5,498,240; 5,507,301; 5,516,336; 5,525,388; 5,533,968; 5,542,925; 5,554,120; 5,554,121; 5,565,523; 5,573,508; 5,632,754; 5,693,015; 5,743,875; 5,747,591; 5,816,923; 5,849,846; 5,868,706; 5,868,767; 5,902,290; 5,993,460; 6,013,069; 6,013,728; 6,027,475; 6,036,707; 6,059,770; 6,061,588; 6,129,707; 6,136,011; 6,139,525; 6,165,152; 6,179,810; 6,206,852; 6,217,547; 6,221,425; 6,224,803; 6,238,376; 6,248,092; 6,251,094; 6,368,301; 6,488,688; 6,572,813; 6,579,484; 6,663,614; 7,273,487. Other U.S. patents pending. Foreign patents issued and pending.

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Graphical Symbols for Medical Device Labeling

Manufacturer	REF Catalogue number	F French size
Do not resterilize	STERILE EO Sterilized using ethylene oxide	Consult instructions for use
Use by	LOT Batch code	Do not reuse
Date of manufacture	Outer diameter	
Contents (numeral represents quantity of units inside)		

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SECTION 11

ENVIRONMENTAL ASSESSMENT

Abbott Vascular claims a categorical exclusion from the requirement that an environmental assessment be performed under 21 CFR 25.24(e)(4). The MINI TREK OTW and TREK OTW Coronary Dilatation Catheters are of the same type and for the same use as other previously approved devices. Also, the approval of this PMA Supplement will not result in the release of substances that, at the expected level of exposure, may be toxic to organisms in the environment. This device will compete for the same market with already approved device in use and, therefore, does not result in increased environmental introduction of the device.

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APPENDIX I – BIOCOMPATIBILITY TEST REPORTS

(Appendix is paginated independently)

Appendix I – 1	Cytotoxicity – ISO Elution Method, MEM Extract
Appendix I – 2	ISO Guinea Pig Maximization Sensitization Test – Extract
Appendix I – 3	ISO Intracutaneous Reactivity
Appendix I – 4	ISO Systemic Toxicity
Appendix I – 5	Hemolysis – Direct Contact and Extraction Methods
Appendix I – 6	Material Mediated Rabbit Pyrogen
Appendix I – 7	LAL Bacterial Endotoxins Test for Medical Devices – Chromogenic Method
Appendix I – 8	Complement Activation C3a
Appendix I – 9	Complement Activation SC5b-9

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APPENDIX A20-I-1

Cytotoxicity – ISO Elustion Method, MEM Extract

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GLP REPORT

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STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Summary

This *in vitro* study was conducted to evaluate TREK OTW for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 24 hours. The negative control (high density polyethylene), reagent control (media alone), and positive control (plasticized vinyl containing 10,10'-oxybisphenoxarsine) were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

The test article extract showed no evidence of causing cell lysis or toxicity and met the requirements of the test since the grade was 0 (no reactivity).

Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak

Carrie-Anne Y. Malinczak, B.S., LAT
Study Director

6-11-10
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

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Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Malinczak, B.S., LAT — Date: 6-11-10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8148.

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1. Introduction

Purpose
The test article, TREK OTW, was extracted and the extract was subjected to an *in vitro* cytotoxicity study to determine whether leachables extracted from the test article would cause cytotoxicity.

Testing Guidelines
The testing procedures are based on the requirements of the International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity.

Dates

Test Article Receipt:	May 13, 2010
Cells Dosed:	May 28, 2010
Observations Concluded:	May 30, 2010

GLP Compliance
The study was initiated by protocol signature on May 24, 2010 and was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

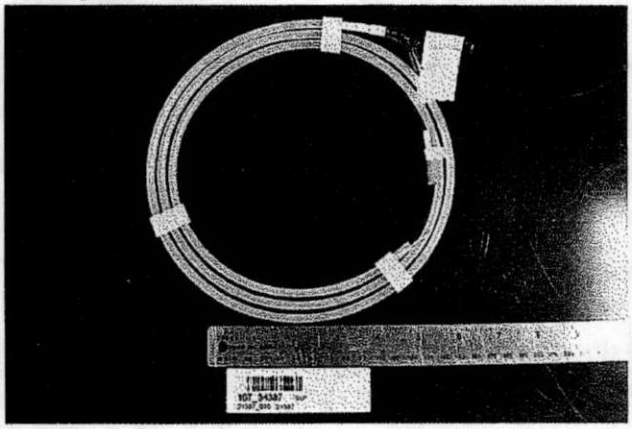
2. Materials

The test article provided by the sponsor was identified and handled as follows:

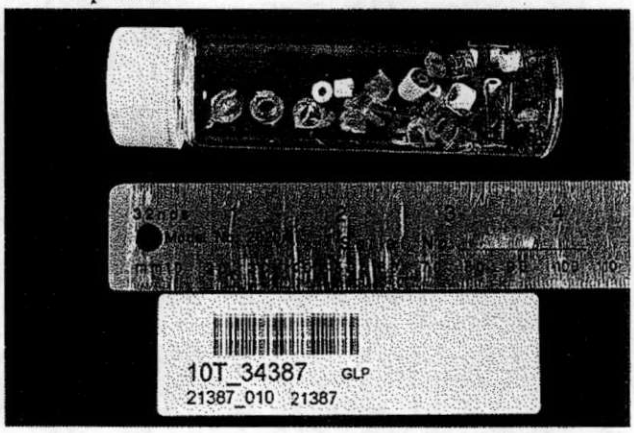
Test Article Name: TREK OTW

Test Article Identification: Part No. 1012404-15, Lot No. 00415N5

Pre-Preparation



Post-Preparation



Stability Testing: In progress (per sponsor)

Expiration Date: Stable for duration of intended testing (per sponsor)

Strength, Purity and Composition: Strength: not applicable because no active ingredients are used to formulate a concentration; Purity: not applicable because the test article is a multi-component device; Composition: Pebax, high-density polyethylene, polycarbonate, Microglide

Physical Description of the Test Article: Catheter

Storage Conditions: Room Temperature

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)

[redacted]

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Erica Hollie 6-11-10

Erica G. Hollie, B.S.
Auditor, Quality Assurance

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-2

ISO Guinea Pig Maximization Sensitization Test – Extract

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

R. Dennis Houlsby
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA 95054

CONFIDENTIAL

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test - Extract

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Appendix 2 - Dermal Reactions Following Challenge Exposure....13
Statement of Quality Assurance Activities....15
NAMSA Lab Number: 10T_29547_01 (Positive Control Study)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The test article, TREK OTW, was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was extracted in 0.9% sodium chloride USP and sesame oil, NF. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal.

The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig and were not considered sensitizers in the guinea pig maximization test.

Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Lisa A. Severhof, B.A.
Supervisor, Toxicology

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak, B.S., LAT
Study Director

7-13-10
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There was one deviation from the protocol (see Page 9) which was not judged to have had any significant impact on the validity or interpretation of the data. There were no other deviations from the protocol, standard operating procedures or the GLP Regulations.

All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Malinczak 7-13-10

Carrie-Anne Y. Malinczak, B.S., LAT Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

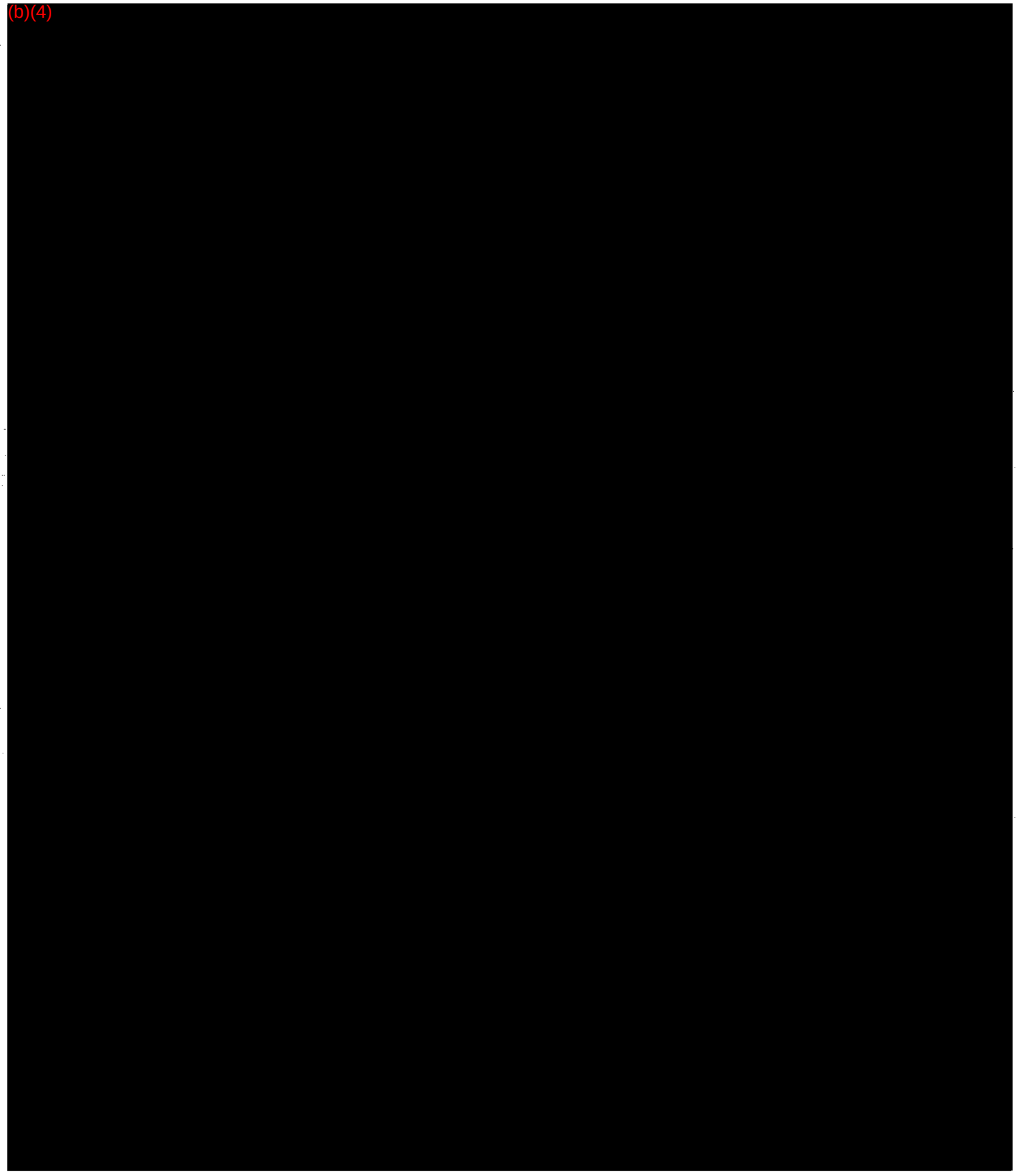
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

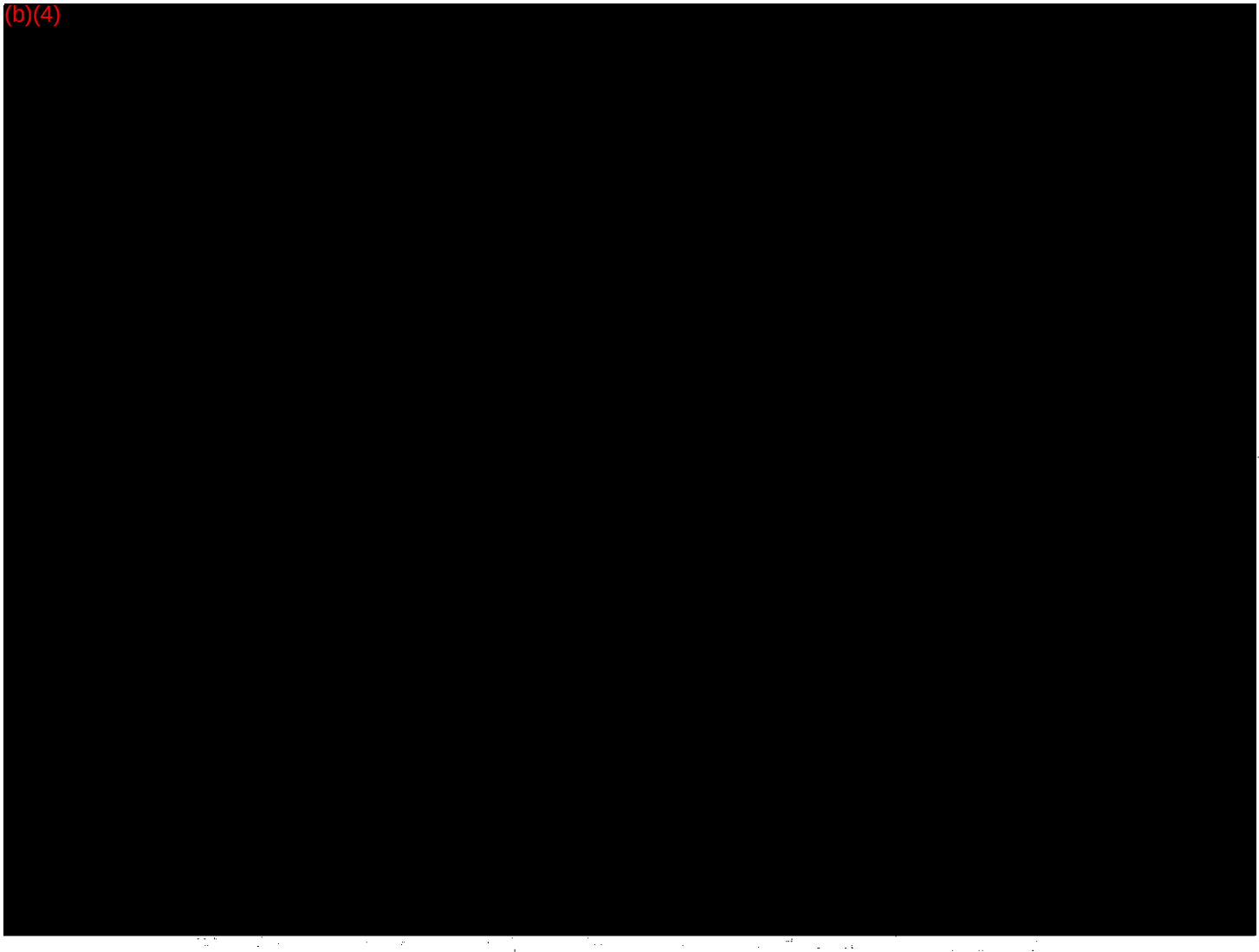
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)

[redacted]

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Debra S Dunn 7-13-10

Debra S. Dunn
Auditor, Quality Assurance

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TEST FACILITY

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419.666.9455

SPONSOR

Julie Judeika
NAMSA Ohio
6750 Wales Road
Northwood, OH 43619

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test - Positive Control

TEST ARTICLE NAME

1-chloro-2,4-dinitrobenzene (DNCB)

TEST ARTICLE IDENTIFICATION

0.1% - Lot: 10-088-T-02
0.01% - Lot: 9-068-T-03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The test article 1-chloro-2,4-dinitrobenzene (DNCB), was evaluated in a guinea pig maximization test (GPMT) to meet the following objectives: 1) confirm the methodology in ISO 10993, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity, 2) substantiate the potential of DNCB to cause delayed contact sensitization, 3) verify proper training of the technologists/technicians performing these studies, and 4) substantiate the susceptibility of the Hartley guinea pig strain to sensitization. The study was conducted based on the requirements of ISO 10993, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity.

A 0.1% (w/w) concentration of DNCB in propylene glycol was intradermally injected and occlusively patched to ten test guinea pigs. The propylene glycol was similarly injected and occlusively patched to five control guinea pigs. Following a recovery period, the test and control animals received a challenge patch of a 0.01% (w/w) DNCB in propylene glycol and the propylene glycol. All sites were scored for dermal reactions at 24 and 48 hours after patch removal.

The known sensitizer DNCB did produce significant evidence of causing delayed dermal contact sensitization in the Hartley strain of guinea pig. Therefore, the following objectives were met: 1) the methodology in ISO 10993, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity was confirmed, 2) the potential of DNCB to cause delayed contact sensitization was substantiated, 3) proper training of the technologists/technicians performing these studies was verified and 4) the susceptibility of the Hartley guinea pig strain to sensitization was substantiated.

Study and Supervisory Personnel:	Colleen M. Stevenson, A.A.	Supervisor, Toxicology
	Lisa A. Severhof, B.A.	Supervisor, Toxicology

Approved by:

Laura L. Tasse, B.S., A.L.A.T.
Study Director

May 28, 2010
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

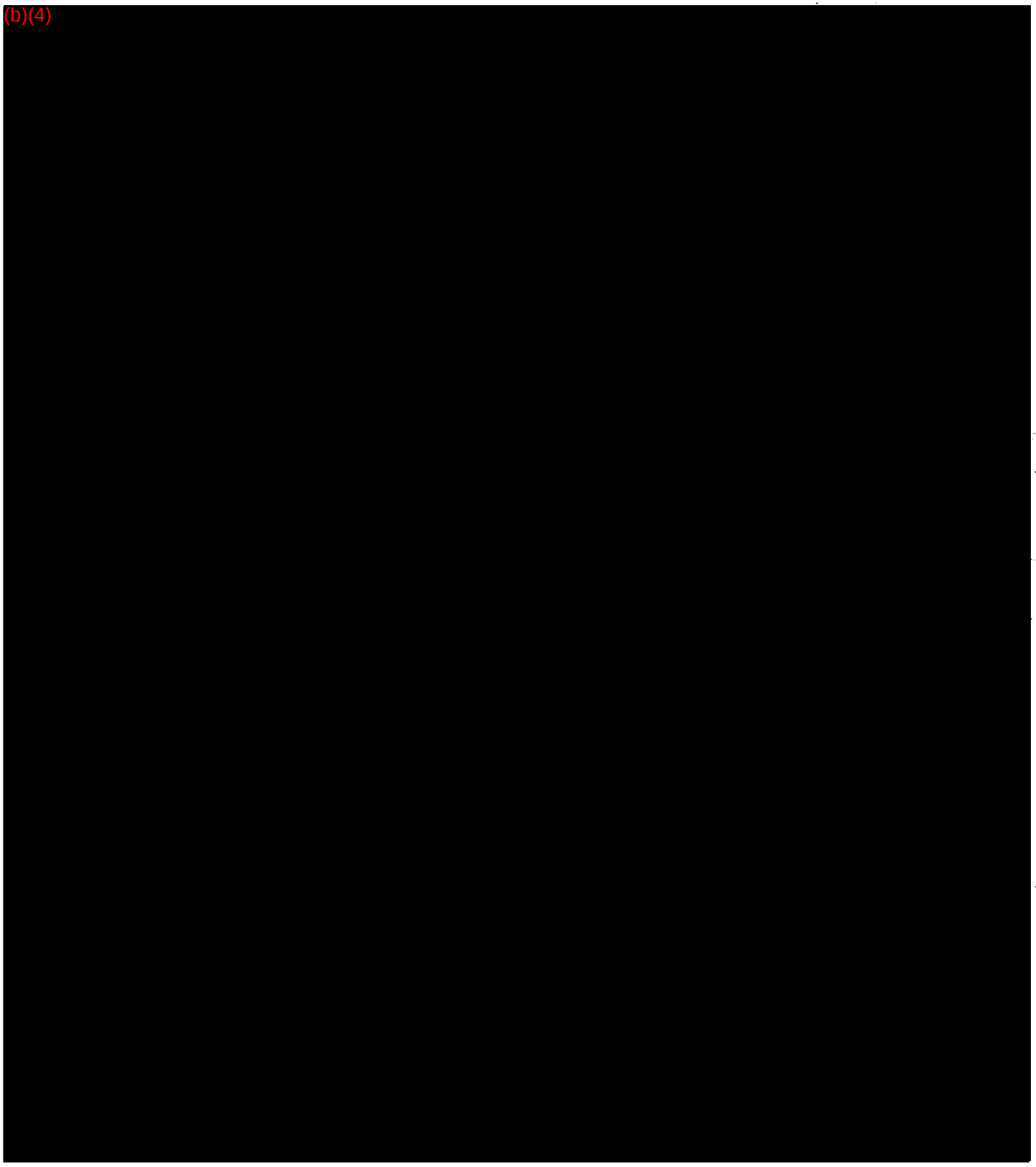
All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Laura L. Tasse, B.S., ALAT — Date: May 28, 2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8188

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

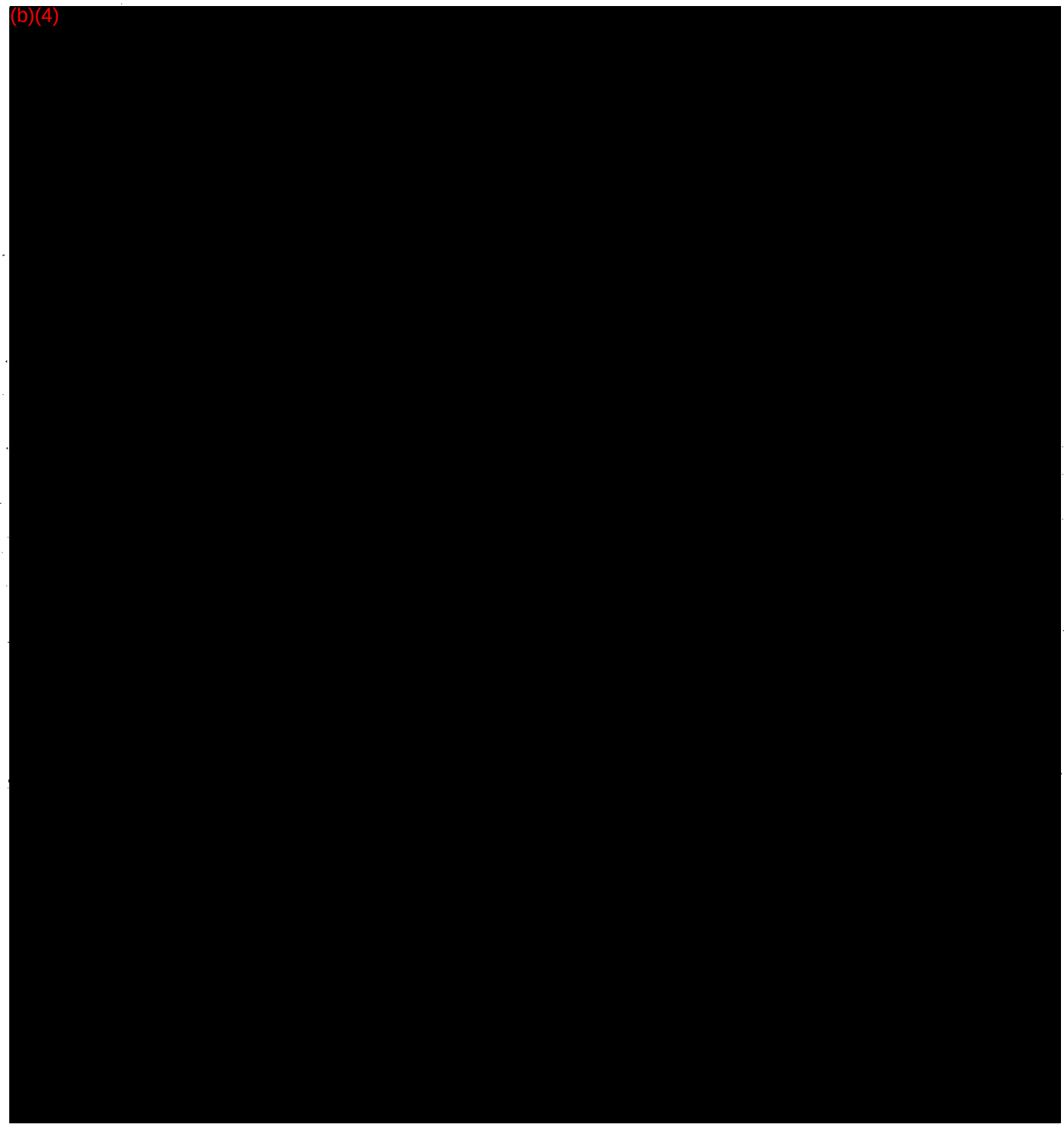
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

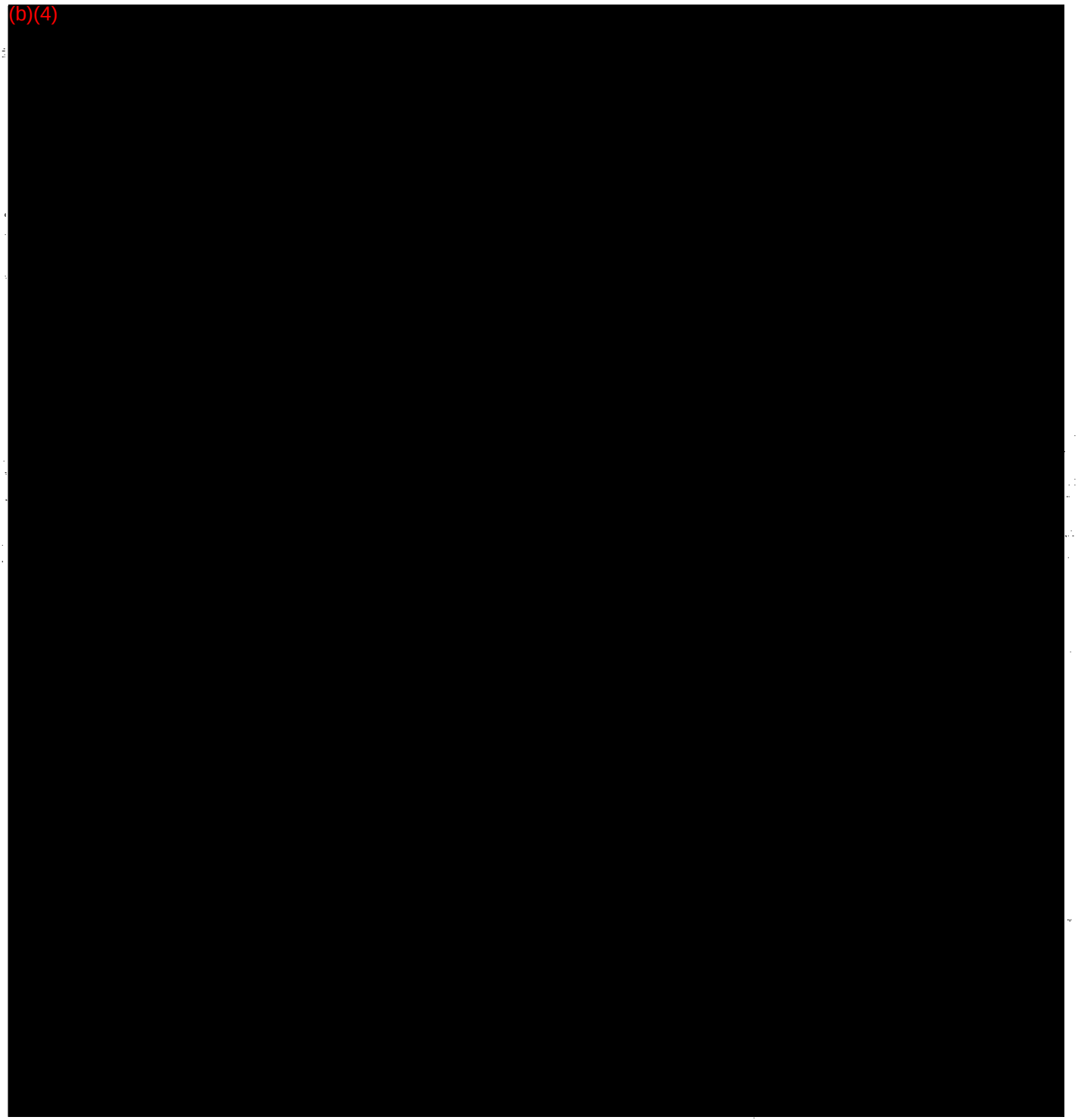
(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

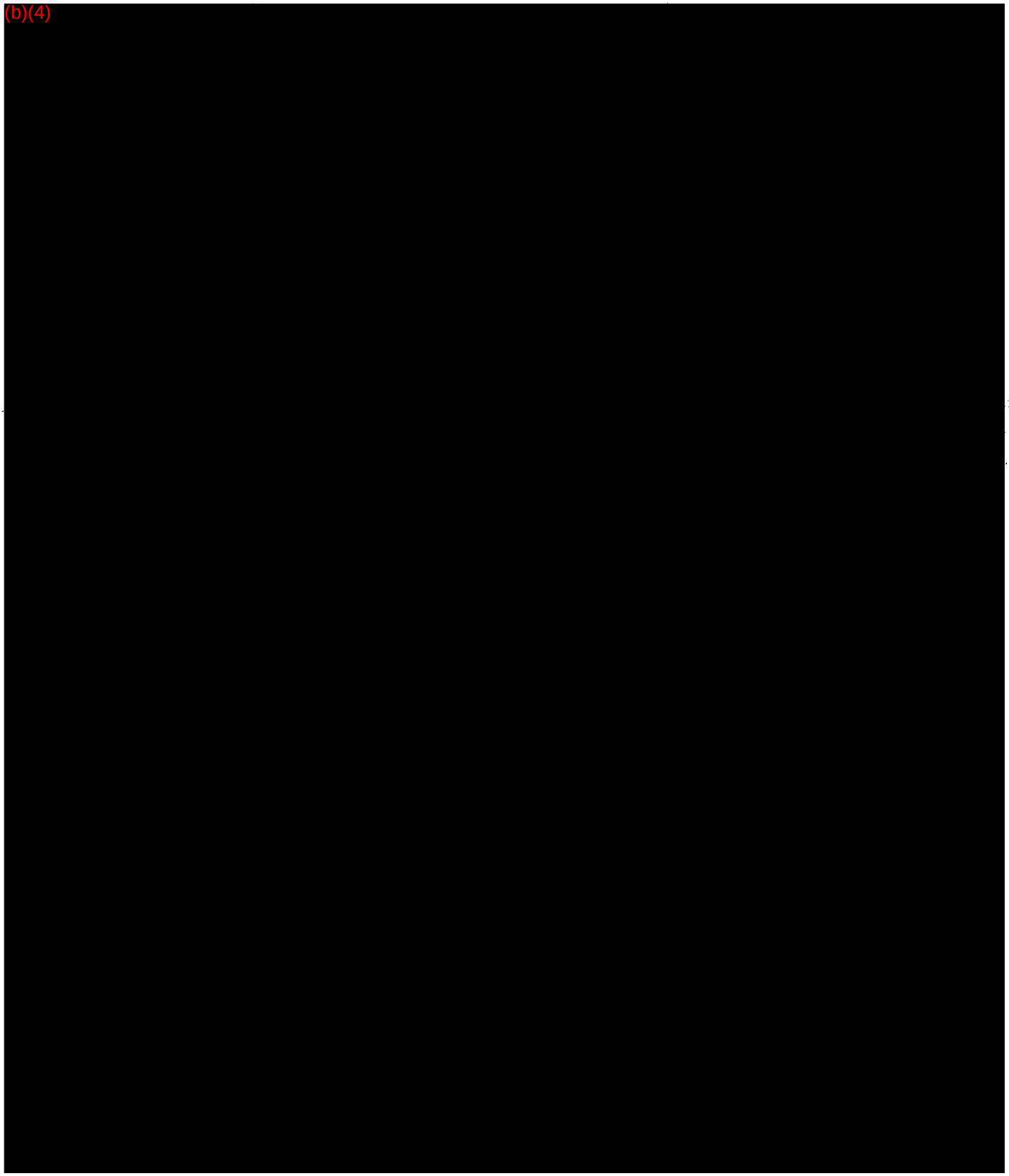
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

11. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies (2008).

Code of Federal Regulations (CFR), Title 9, Parts 1-199, Animal Welfare Act (2008)

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 1996.

Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals.

International Organization for Standardization (ISO) 10993, Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements (2006).

International Organization for Standardization (ISO) 10993, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity (2002).

Organisation for Economic Co-operation and Development (OECD), Guideline for Testing of Chemicals, Number 406, Skin Sensitisation (1992).

Frankild, S., Basketter, D.A., and Andersen, K.E. The value and limitations of rechallenge in the guinea pig maximization test. *Contact Dermatitis* 35:135-140, 1996.

Kligman, A.M. and Basketter, D.A. A critical commentary and updating of the guinea pig maximization test. *Contact Dermatitis* 32:129-134, 1995.

Magnusson, B. and A. Kligman, *Allergic Contact Dermatitis in the Guinea Pig* (Springfield: C.H. Thomas, 1970).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Appendix 3 - Certificate of Analysis

Lot 10-088-T-02

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Lot 9-068-T-03

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)

[redacted]

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Susan Pellitieri 5-25-10

Susan Pellitieri, B.A.
Reviewer, Quality Assurance

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-3

ISO Intracutaneous Reactivity

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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GLP REPORT

TEST FACILITY

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Northwood, OH 43619
419.666.9455

SPONSOR

R. Dennis Houlsby
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA 95054

CONFIDENTIAL

STUDY TITLE

ISO Intracutaneous Study in Rabbits - Extract

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The potential for components from the test article, TREK OTW, to cause irritation following intracutaneous injection in rabbits was evaluated based on ISO 10993-10: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was extracted in 0.9% sodium chloride USP solution (SC) and sesame oil, NF (SO). A 0.2 mL dose of the appropriate test article extract was injected intracutaneously into five separate sites on the right side of the back of each of two animals. Similarly, the extract vehicle alone (control) was injected on the left side of the back of each animal. The injection sites were observed immediately after injection. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection.

There was no erythema and no edema from the SC test extract injected intracutaneously into rabbits. There was very slight erythema and very slight edema from the SO test extract injected intracutaneously into rabbits. Each test article extract met the requirements of the test since the difference between the overall test extract mean score and overall corresponding control mean score was 0.0 for the SC and SO test article extracts.

Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak B.S., LAT — Date Completed: 6-14-10
Study Director

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

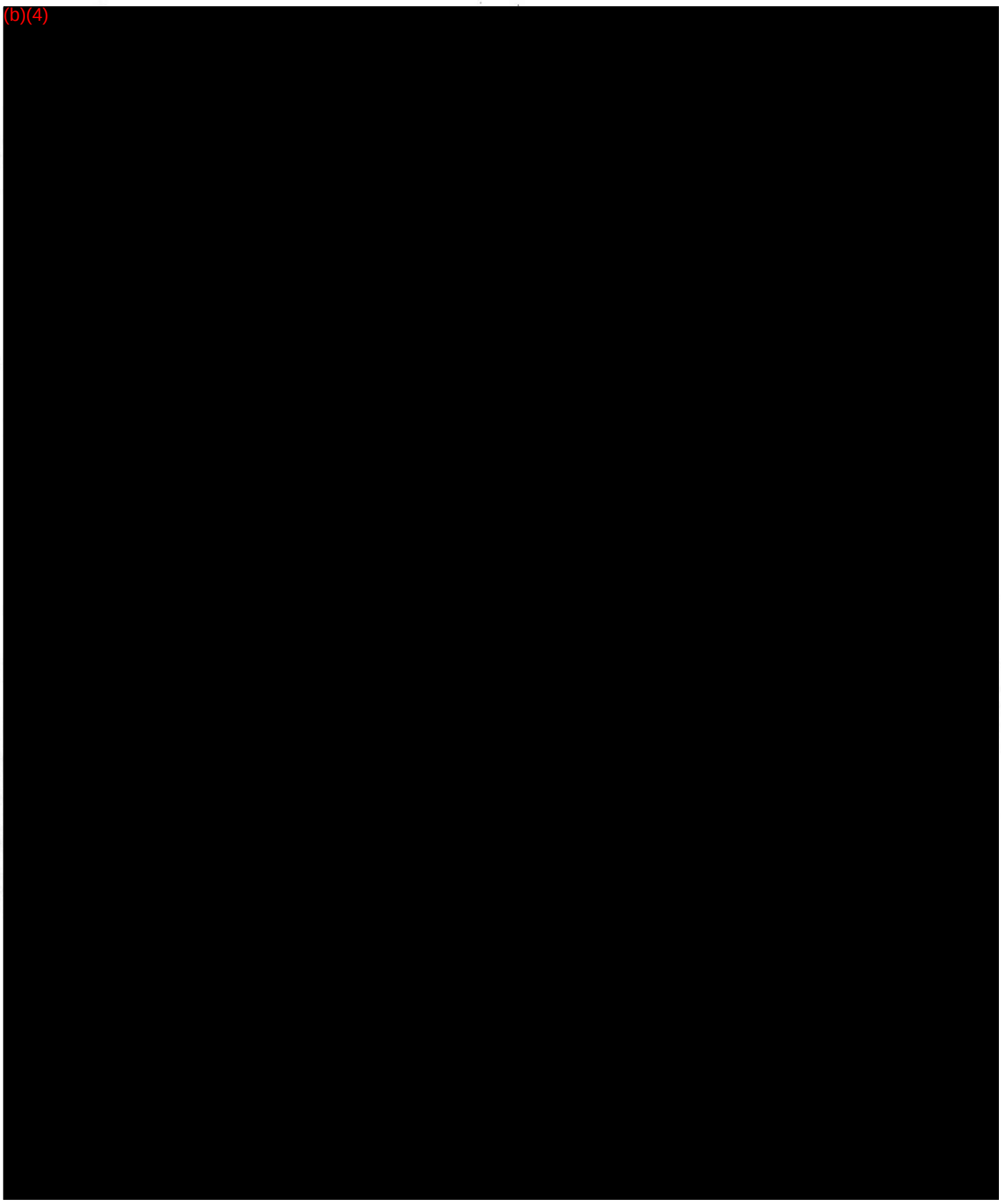
All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Malinczak, B.S., LAT 6-14-10 Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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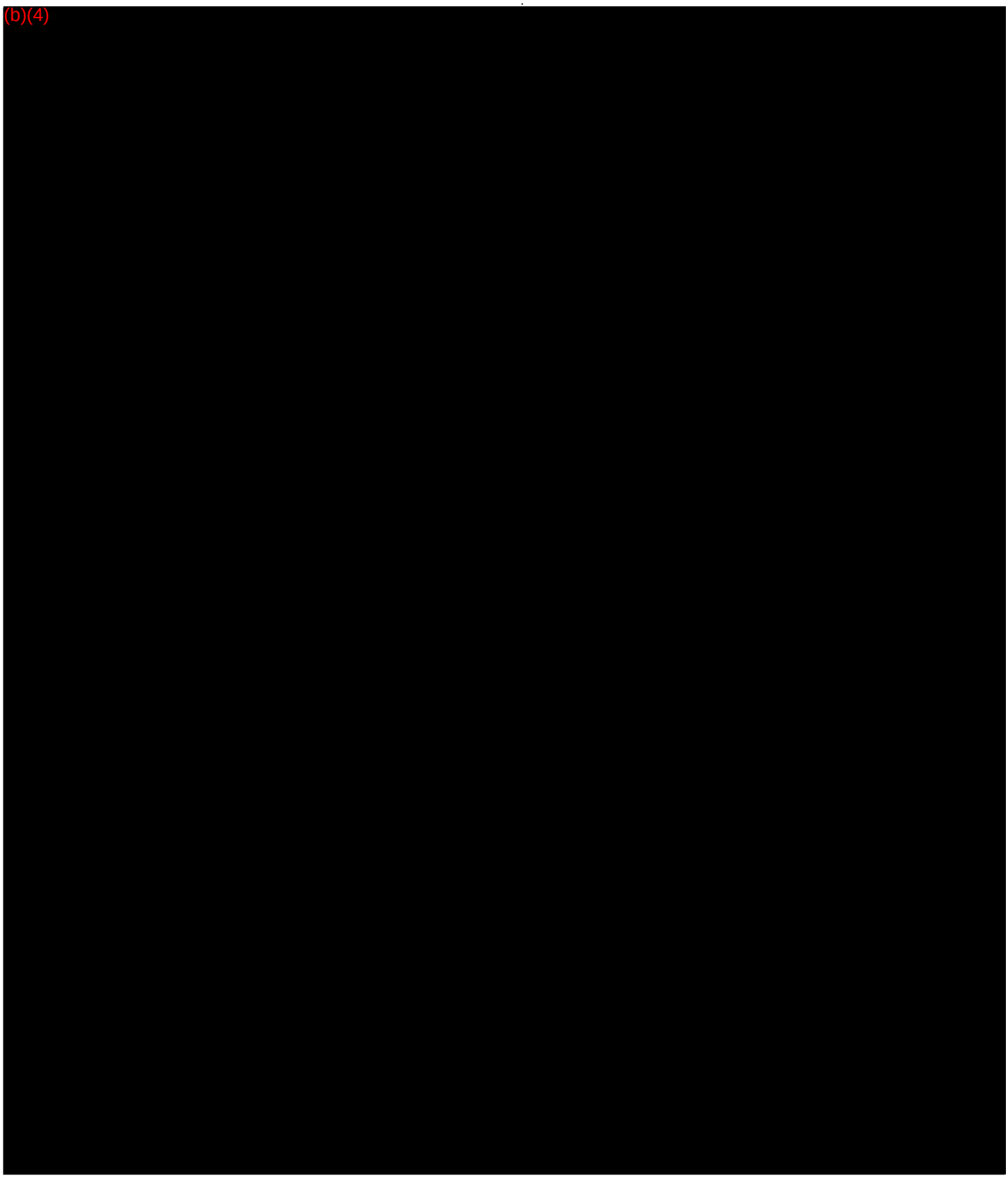
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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Heather A. Saums B.S., ALAT
Reviewer II, Quality Assurance

6-14-10
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-4

ISO Systemic Toxicity

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

GLP REPORT

TEST FACILITY

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SPONSOR

R. Dennis Houlsby
Abbott Vascular
3200 Lakeside Drive
Santa Clara, CA 95054

CONFIDENTIAL

STUDY TITLE

ISO Systemic Toxicity Study in Mice - Extract

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The test article, TREK OTW, was evaluated for acute systemic toxicity in mice based on International Organization for Standardization 10993-11, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity. The test article was extracted in 0.9% sodium chloride USP solution and sesame oil, NF. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals was dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on Days 1, 2 and 3.

There was no mortality or evidence of systemic toxicity from the extracts. The test article extracts met the requirements of the study.

Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak, B.S., LAT
Study Director

6-14-10
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

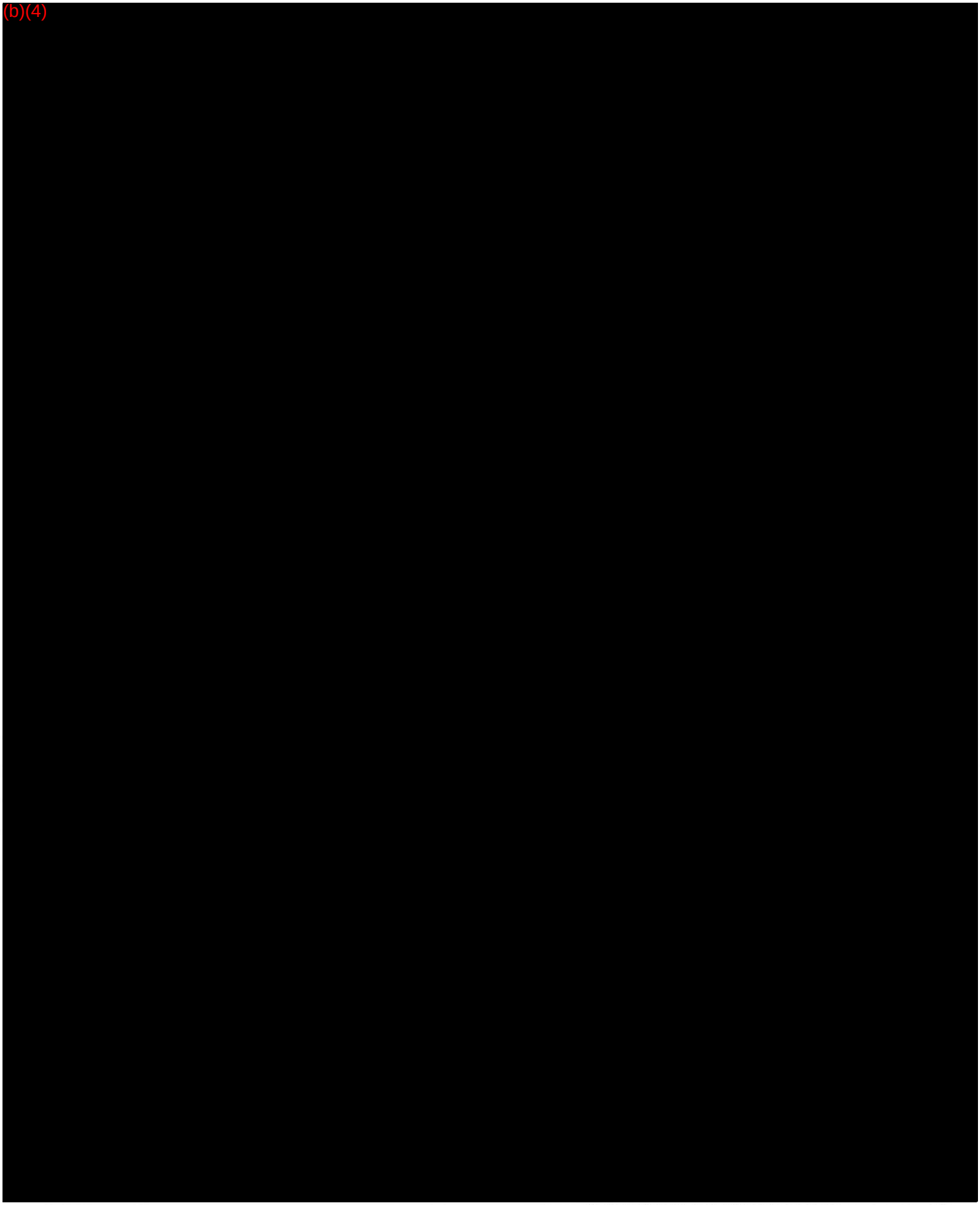
All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Malinczak, B.S., LAT 6-14-10 Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

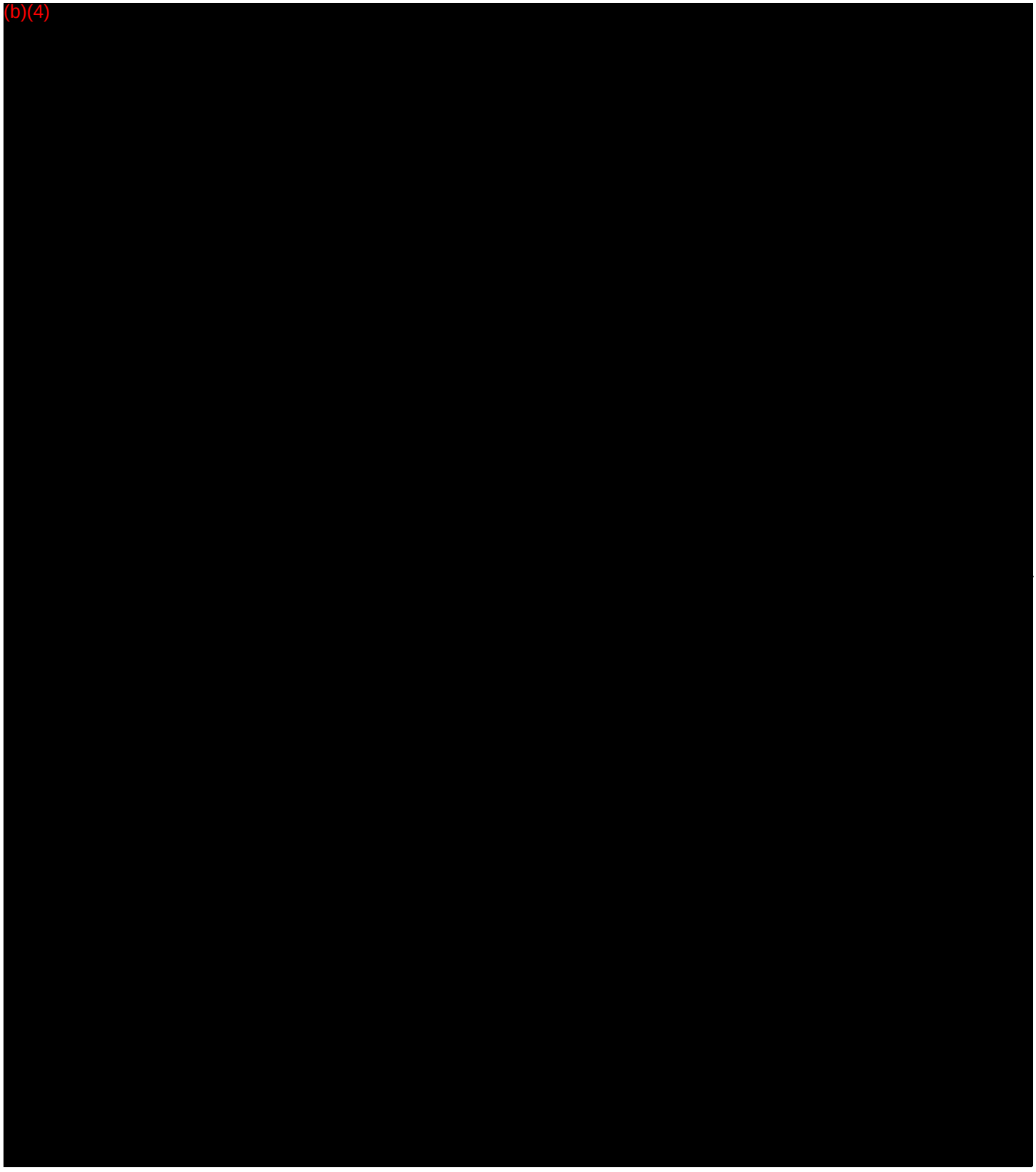
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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(b)(4)



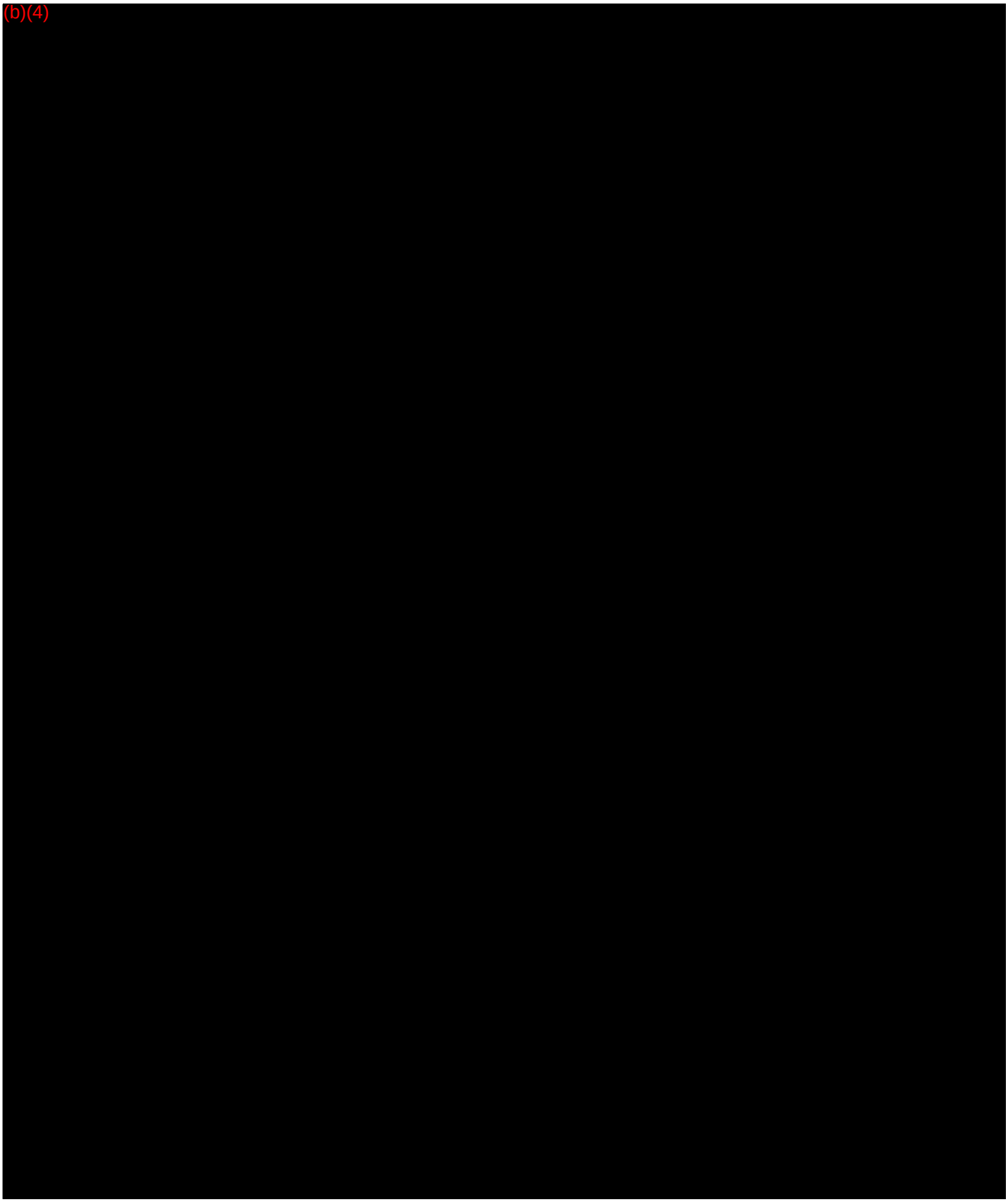
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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)



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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)

[redacted]

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: _____ 6-14-10

Lisa M. Byrd, RQAP-GLP, CQA, ALAT
Auditor, Quality Assurance

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-5

Hemolysis – Direct Contact and Extraction Methods

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8188

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

GLP REPORT

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CONFIDENTIAL

STUDY TITLE

ASTM Hemolysis

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The test article, TREK OTW, was evaluated based on ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials and also per the requirements of ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions With Blood. Blood was obtained from three rabbits, pooled, diluted, and added to triplicate tubes with the test article in calcium and magnesium-free phosphate buffered saline (CMF-PBS) and triplicate tubes with the CMF-PBS test article extract. These combinations were evaluated to determine whether the test article in direct contact with blood or an extract of the test article mixed with blood would cause *in vitro* red blood cell hemolysis. Negative controls, positive controls, and blanks were prepared in the same manner as the test article. Each tube was inverted gently to uniformly mix the contents with the blood. The tubes were then maintained for at least 3 hours at 37°C with periodic inversions. Following incubation, suspensions were mixed gently and centrifuged. The resulting supernatant was added to hemoglobin reagent. The absorbance of each solution was spectrophotometrically measured at a wavelength of 540 nm.

The hemolytic index for the test article in direct contact with blood was 0.0%, and the hemolytic index for the CMF-PBS test article extract was 0.1%. The test article in direct contact with blood was non-hemolytic and the test article extract was non-hemolytic.

Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

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Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak, B.S., LAT
Study Director

6-14-10
Date Completed

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There was one deviation from the protocol (see Page 9) which was not judged to have had any significant impact on the validity or interpretation of the data. There were no other deviations from the protocol, standard operating procedures or the GLP Regulations.

All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Maliszak 6-14-10

Carrie-Anne Y. Maliszak, B.S., LAT Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

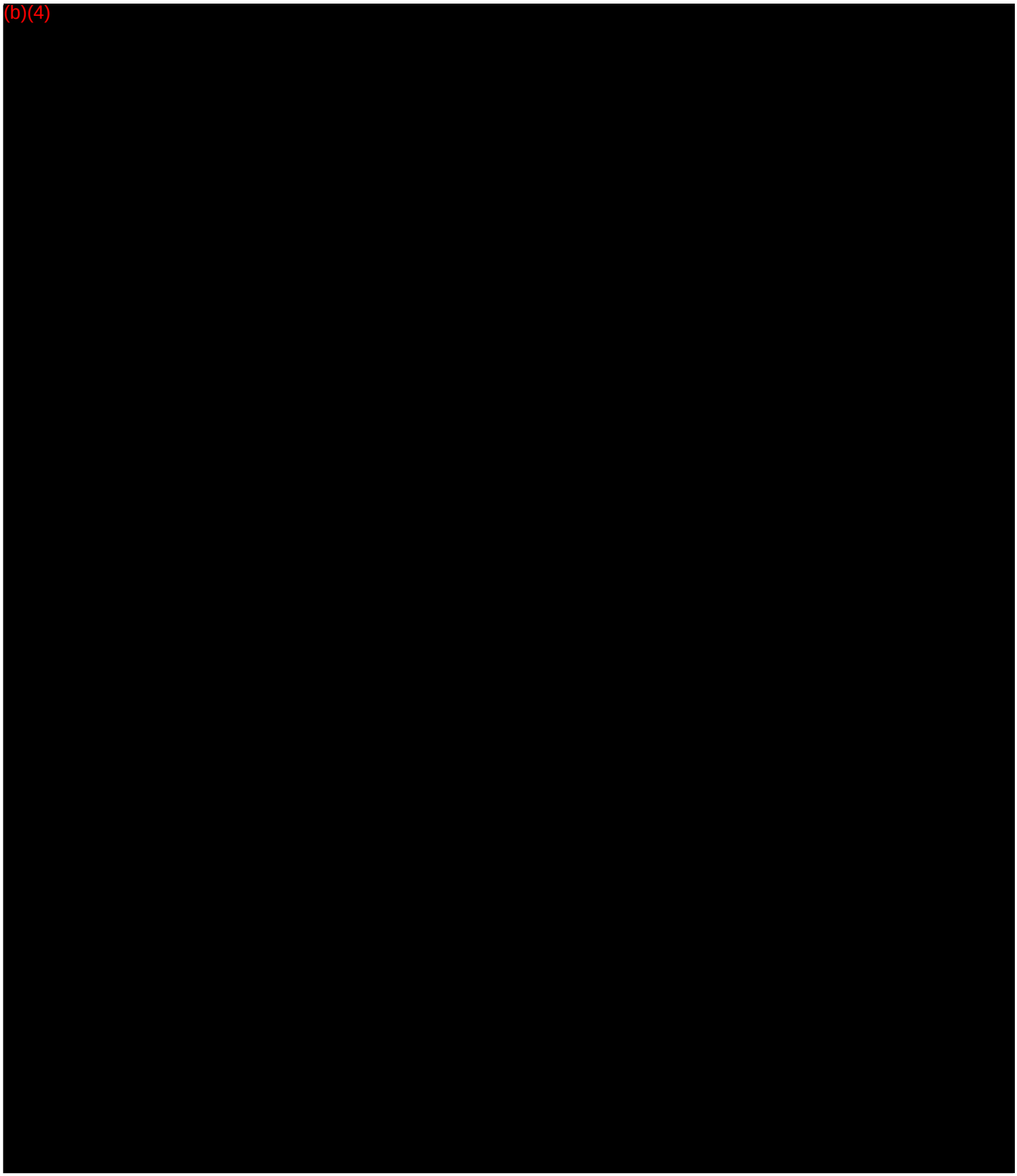
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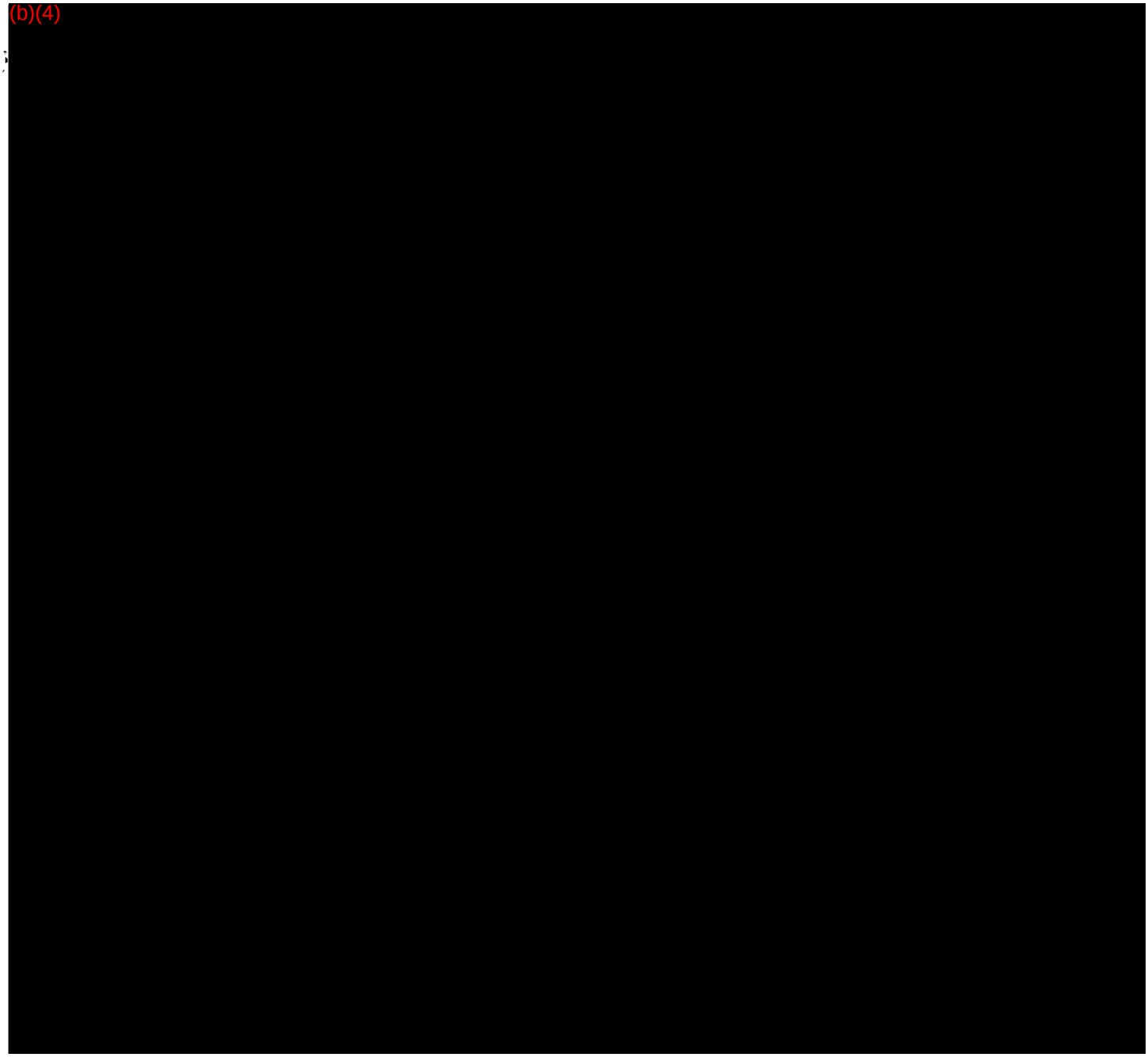
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(b)(4)

[redacted]

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Susan Pellitieri 6-14-10

Susan Pellitieri, B.A.
Reviewer, Quality Assurance

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-6

Material Mediated Rabbit Pyrogen

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8116.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

GLP REPORT

TEST FACILITY

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SPONSOR

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CONFIDENTIAL

STUDY TITLE

USP Pyrogen Study - Material Mediated

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8108.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The test article, TREK OTW, was extracted in sterile, nonpyrogenic 0.9% sodium chloride solution. The test extract was evaluated in the rabbit for material mediated pyrogenicity. The test was conducted based on USP, General Chapter <151>, Pyrogen Test. The procedure is recommended in ISO 10993, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity.

A single dose of 10 mL/kg was intravenously injected via the marginal ear vein into each of three animals. Rectal temperatures were measured and recorded prior to injection and at 30 minute intervals between 1 and 3 hours after injection.

The total rise of rabbit temperatures during the 3 hour observation period was within acceptable USP limits. The test article was judged as nonpyrogenic.

Supervisory Personnel:

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Manager, Technical Sales and Services

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak, B.S., LAT
Study Director

6-14-10
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8148.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

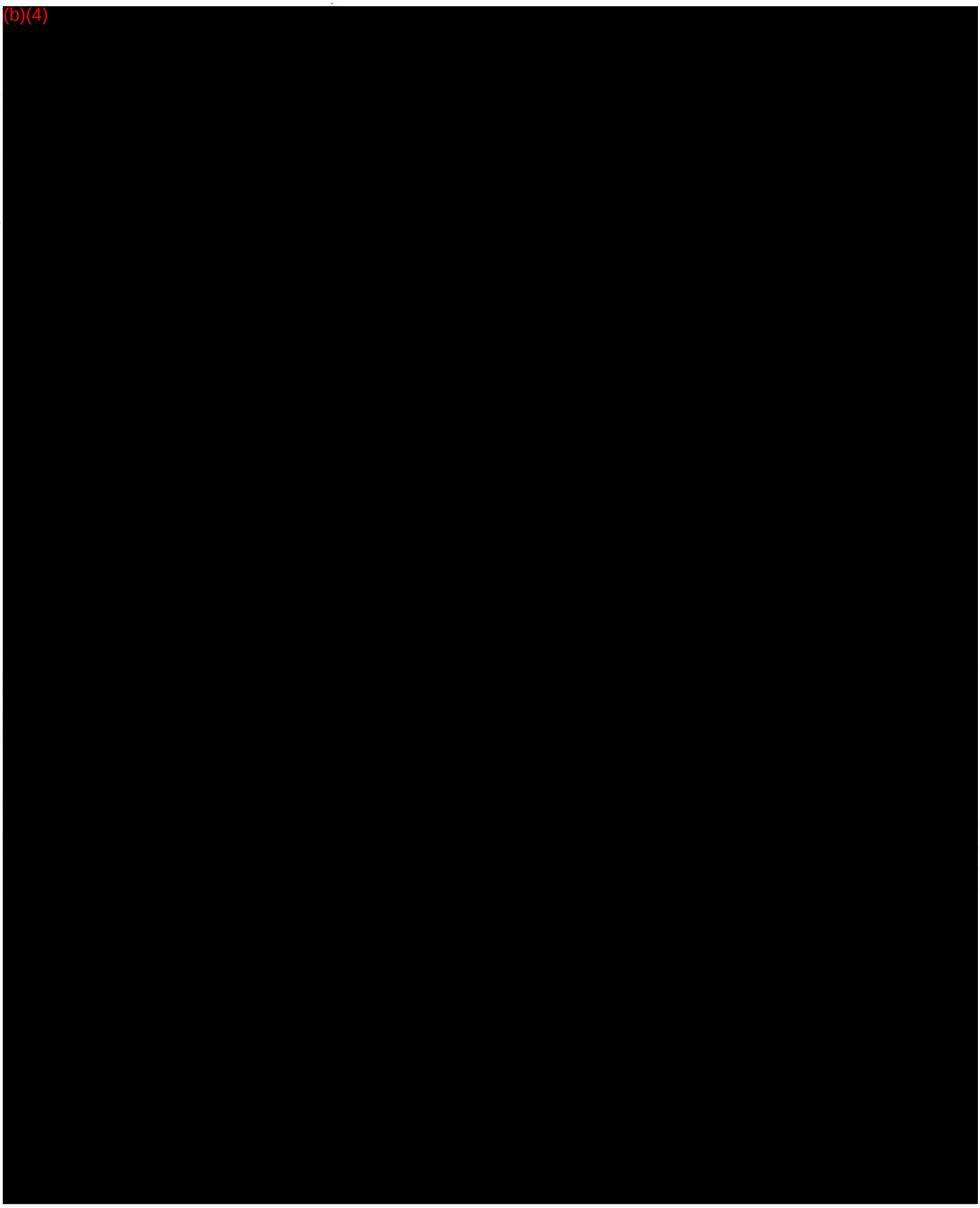
All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Malinczak, B.S., LAT 6-14-10 Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

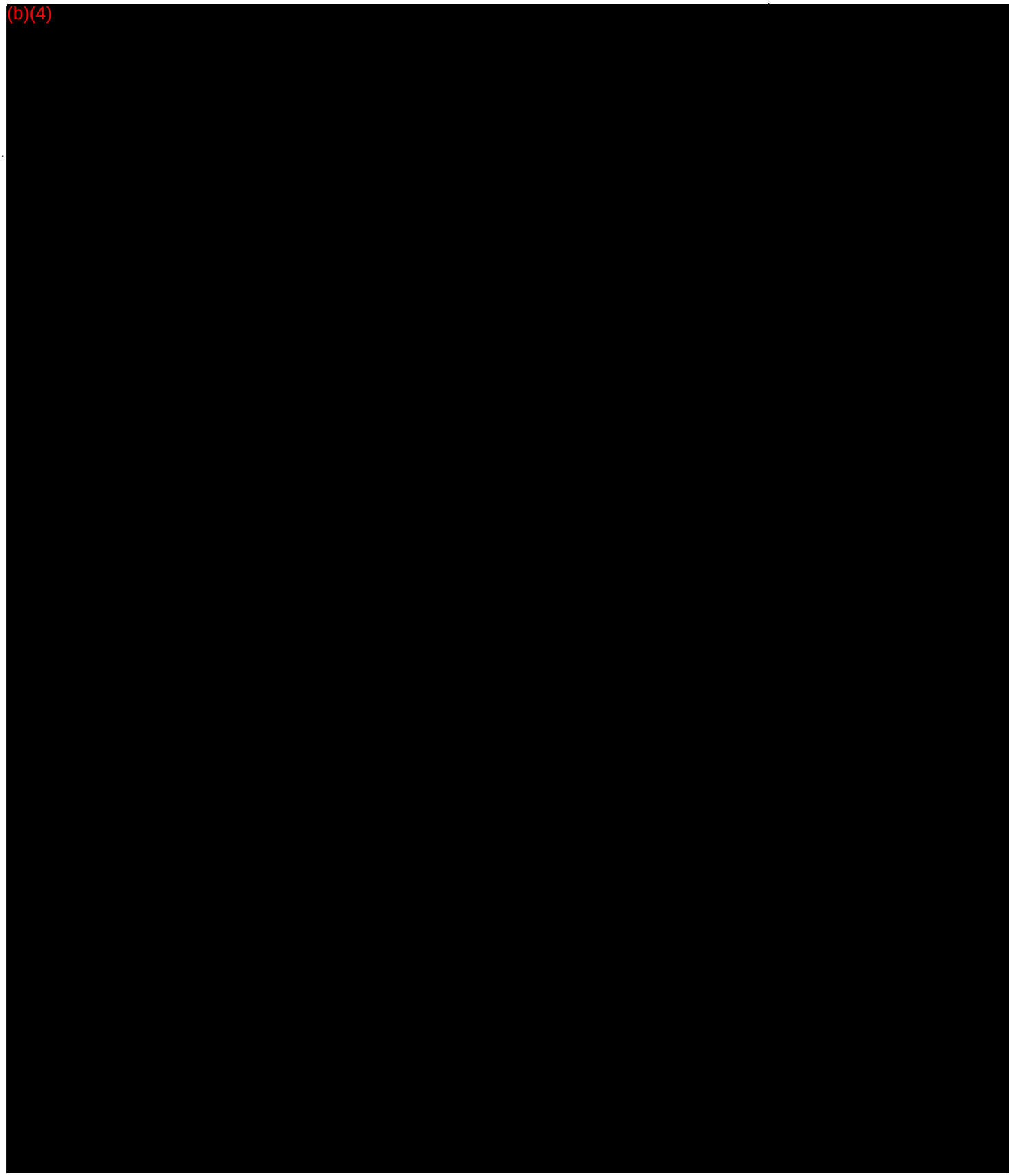
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4)

[redacted]

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: _____ 6-14-10

Heather A. Saums B.S., ALAT
Reviewer II, Quality Assurance

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-7

LAL Bacterial Endotoxins Test for Medical Devices – Chromogenic Method

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-8

Complement Activation C3a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

GLP REPORT

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3200 Lakeside Drive
Santa Clara, CA 95054

CONFIDENTIAL

STUDY TITLE

C3a Complement Activation Assay

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The test article, TREK OTW, was evaluated for the potential to activate the complement system. This study was conducted *in vitro* by incubating the test article in normal human serum (NHS) and detecting the presence of C3a in the exposed serum by an enzyme immunoassay method. The C3a concentration from the test article sample was compared statistically to activated NHS and negative (low density polyethylene) controls.

The C3a concentration of the test article sample was 11,712 ± 423.7 ng/mL (mean ± standard deviation) and was statistically higher than the activated NHS control and the negative control, and was 9.90% of a positive biomaterial reference control (latex). The C3a concentration in the test sample was less than the historical ranges of the activated NHS and negative controls. As a result, the test article was considered to be a low potential activator of the complement system.

Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak
Carrie-Anne Y. Malinczak, B.S., LAT
Study Director

7-2-10
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Malinczak, B.S., LAT 7-2-10 Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 896

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

APPENDIX A20-I-9

Complement Activation SC5b-9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

GLP REPORT

TEST FACILITY

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CONFIDENTIAL

STUDY TITLE

SC5b-9 Complement Activation Assay

TEST ARTICLE NAME

TREK OTW

TEST ARTICLE IDENTIFICATION

Part No. 1012404-15, Lot No. 00415N5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Summary

The test article, TREK OTW, was evaluated for the potential to activate the complement system. This study was conducted *in vitro* by incubating the test article in normal human serum (NHS) and detecting the presence of SC5b-9 in the exposed serum by an enzyme immunoassay method. The SC5b-9 concentration from the test article sample was compared statistically to activated NHS and negative (low density polyethylene) controls.

The concentration of SC5b-9 in the test article sample was 4,413 ± 269.2 ng/mL (mean ± standard deviation) and was statistically higher than the activated NHS control and the negative control, and was 4.4% of the positive biomaterial reference control (latex). The SC5b-9 concentration in the test article sample was less than the historical range of the activated NHS and negative controls. As a result, the test article was considered to be a low potential activator of the complement system.

Supervisory Personnel:

Don R. Pohl, B.S.
Manager, Technical Sales and Services

Melissa A. Cadaret, B.A., M.S.
Manager, Toxicology

Approved by:

Carrie-Anne Y. Malinczak, B.S., LAT
Study Director

7-2-10
Date Completed

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There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data have been accurately recorded and verified, as indicated by the signature below.

Study Director: Carrie-Anne Y. Malinczak 7-2-16

Carrie-Anne Y. Malinczak, B.S., LAT Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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TREK™ and MINI TREK™ RX and OTW CDC Risk Assessment Report

Date Updated: July 14, 2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Device Description	The TREK RX is a Rapid Exchange (RX) Coronary Dilatation Catheter and the TREK OTW is an over-the-wire Coronary Dilatation Catheter. The device families range in size from 1.20mm - 5.00mm diameters and 6-30mm lengths with a total of 77 sizes for each platform.

Device Application	The TREK RX, MINI TREK RX, TREK OTW and MINI TREK OTW CDC are intended for the following uses: • Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. • Balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction. • Balloon dilatation of a stent after implantation. The following factors were considered in preparing this Risk Assessment: **Human Factors (User-related)** • Contamination • Incorrect prep (i.e. prep with positive pressure) • Incorrect catheter system removal • Shaft kinking • Crossing previously deployed stent • Not following Instructions for Use (IFU) **Environmental Conditions** • Procedure performed in Cardiac Catheterization Laboratory • Ambient temperature of approximately 60°F (up to 95% humidity) • Patient body temperature of 37°C • Device contact with blood • Contact with coronary vessels, lesions, and possibly previously implanted stents **Device Interactions** • Indeflator/Inflation device • Introducer • Guidewire • RHV • Guiding Catheter • Other stents and delivery systems • Dilatation catheters • Retrieval devices (snares, alligator forceps) • Debulking devices • Luer-Lock Syringes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Scope	This risk assessment report pertains to the entire TREK RX CDC, MINI TREK RX CDC, TREK OTW CDC and MINI TREK OTW CDC. TREK RX and MINI TREK RX will be referred to as TREK RX and TREK OTW and MINI TREK OTW will be referred to as TREK OTW from this point forward. The purpose of the Risk Assessment is to analyze the product designs and processes for product hazards with respect to safety and functional hazards for the physician/clinician and patient. Results of the risk assessment will be presented at appropriate project reviews in accordance with SOP677. Revisions to the risk assessment report will be controlled by the change management system and will be archived as RAM1012066 in Viewpoint. The TREK RX and TREK OTW assessment will be based on the predicate devices (VOYAGER™ RX CDC and VOYAGER™ OTW CDC) with respect to the device use, application, manufacturing processes, and process controls. The TREK RX and TREK OTW designs introduce new processes and technologies, designs and materials; however, no new device applications and/or indications will be introduced with the TREK RX/OTW CDC. The TREK RX and OTW risk analysis is being combined due the similarity between the device designs and the fact that numerous manufacturing processes are shared between the two device platforms. The initial Phase I TREK/MINI TREK OTW (Xcalibur was the project name) is located in Viewpoint as RAM1011966 Rev 1 and has been superceded by this document. The risk analysis worksheets include a Design Failure Mode Effect Analysis (FMEA), Process FMEA, Use FMEA and Component FMEA. The Design and Component FMEA are organized by specific catheter item/function or component, respectively. The Process FMEA is organized by process on the LHRBM and the Use FMEA is organized by procedural step. All FMEAs contain columns that denote RX and OTW to specify which line items in the risk assessment worksheet are applicable to RX, OTW or both device platforms.

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Scope (continued)	The following table contains the RAM1012066 Revision History:

Revision	Summary of Changes
1	▪ Xcalibur RX- Initial Release Phase I
2	▪ Changed name from Xcalibur (project name) to TREK (product name) ▪ Updated format to DFMEA, PFMEA, UFMEA, CFMEA ▪ Added Phase II information
A	▪ Added Phase III information
B	▪ Changed 1.25mm balloon size to 1.20mm ▪ Corrected typographical errors
C	▪ Added TREK and MINI TREK OTW Phase I and superceded Xcalibur OTW RAM1011966
D	▪ Includes TREK and MINI TREK OTW Phase II
E	▪ Includes TREK and MINI TREK OTW Phase III ▪ Changed severity for Ischemia from S-3 to S-2 per DOP489 Rev BG

Document References (Document Number/Rev)	RAM2036407/G- Risk Assessment Report VOYAGER™ RX CDC RAM1011287/E – VOYAGER™ OTW Risk Assessment SOP5547/A– Global Risk Management Process DOP678/AA– Product Development Risk Management - Legacy DOP489/BG– Complaint Coding Manual for VIPER LHRBM102268/H – TREK RX & MINI TREK RX CDC XLHRBM1012401/14– TREK OTW & MINI TREK OTW CDC PS1012268/J– TREK and MINI TREK Product Specification PS1012401/H – TREK OTW and MINI TREK OTW PS DDD2061559/C – TREK RX and mini TREK RX DDD DDD1012401/C – TREK OTW and MINI TREK OTW DDD QS1012268/G – TREK and MINI TREK RX Finished Device Audit QS1012401/A - TREK and MINI TREK OTW Finished Device Audit RPT2073279/A – TREK and MINI TREK RX Filing Report RPT2070662-12A,-24A/A–TREK and MINI TREK RX Aging Report VRP1012268/B – TREK and MINI TREK RX Performance Qualification RPT2075667/A – TREK and MINI TREK OTW Filing Report RPT2075504-1A/A – TREK and MINI TREK OTW Aging Report VRP1012401/A – TREK and MINI TREK OTW Performance Qualification

Assumptions	The following assumptions were used when evaluating the overall risk of the TREK RX and TREK OTW. In summary these assumptions entail that the device will be used properly, as instructed

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Assumptions (continued)	and labeled, and by trained personnel. • Device will be properly transported and stored • Physician will be fully trained • Device will be used only with compatible guide wires and guiding catheters • Patient will have positive coronary ischemia • Device will be used in coronary vessels size 1.20 – 5.0mm • Device will be used with products that are within their respective product specifications • Product will be used within its shelf-life • Device will be used one at a time only • Original occurrence rates assume that line clearance, line audits, finished device audits and training to documentation have been implemented • Occurrence rates and severity levels for similar hazards and causes are expected to be similar to predicate devices

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Design Related Hazards

The TREK RX and TREK OTW design is intended to address many user needs; however, only one of which is unique to this product. This user need is the ability to reach distal lesions, which consequently results in a smaller vessel ID. As a result of this user need, TREK RX/OTW will be offered in a 1.20mm diameter balloon size. The 1.20mm balloon will be immediately available in the European Union as well as Japan. There are no new hazardous conditions expected with the 1.20mm balloon size.

The overall goal of TREK RX/OTW is to become best-in-class in terms of performance. In order to achieve this, a number of new materials, dimensions, designs and technologies have been incorporated into the design and evaluated for new potential failure modes, reference Table 1 below. Each of these new potential failure modes has been addressed in the Phase II Risk Analysis Worksheet (RAW), reference Appendix A.

Table 1: New Designs/ Materials utilized by TREK RX/OTW

Feature	Design/Process/Material	History
Balloon	Process - Double blow	Makes balloon blow set-up parameters less sensitive and reduces the calculated standard deviation of balloons blown with the same set-up.
	Process – Balloon milling (2.00 – 3.75mm) distal balloon shaft	Reduces profile, increases flexibility of tip
	Material – 63D/72D Co-extrusion (2.25-5.00mm)	Co-extrusion improves balloon compliance
Balloon	Material – 70D (1.20 – 2.00mm)	Allows for thicker walls and improved material strength
Inner Member (IM)	Process – necked IM	Reduces profile under balloon
	Material - 72D thin HDPE (trilayer)	Provides best performance
Distal Outer Member (OM)	Process - Blown DOM	Increases rupture strength
	Material - 63D/72D co-extrusion	Ruptures longitudinally which reduces separation risk

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Design Related Hazards (continued)

Table 1: New Designs/ Materials utilized by TREK RX/OTW (continued)

Feature	Design/Process/Material	History
Marker Bands	Process – Tungsten marker bands cut with Accucut, laser-bonded to IM	Lasered marker bands more consistent in length using Accucut and laser process
Soft Tip	Tip through design (tip bonded to IM and seal is located inside balloon)	Improves transition of stiffness by increasing the flexibility of the distal balloon taper and shaft, reduces tip crossing profile
Distal Seal	Process - Short seal and no unsealed balloon shaft	Improves transition of stiffness by increasing the flexibility of the distal balloon taper and shaft
Outer Member-hypotube (RX only)	Process - Heat bonder	Creates smooth seal
IM Coating	Material - Microglide	Reduces resistance between GW and IM
Hydrophilic coating	Material - Double coat (PEO/PEO)	Increases coating durability and reduces coating friction
Proximal Shaft component (RX only)	Proximal shaft assembly will be vendor supplied and include the sidearm, hypotube, skive (distal end of hypotube for junction support) and proximal shaft markers	Reduces cost
Proximal shaft (OTW only)	TR55/72D Pebax Co-extruded tapered shaft	Tapered shaft eliminates need for Midshaft and TR55 provides stiffness to optimize the "push" of the catheter

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Comparison to Similar Devices	The general design of the TREK RX and TREK OTW will be similar to the design of the RX VOYAGER™ CDC and OTW VOYAGER™ CDC, respectively. The distal shaft (entire shaft for OTW) is co-axial with a balloon at the distal tip. The outer lumen provides for inflation of the balloon with contrast medium. The central lumen permits the guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon has two radiopaque markers (one center marker for 1.20mm, 1.5mm diameters and 6mm length) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at specified pressures. Proximal shaft markers located on the outer shaft aid in gauging the dilatation catheter position relative to the guiding catheter tip when introducing the catheter through the guiding catheter. An adaption arm is provided on the proximal end of the catheter to provide access to the inflation lumen. It is designed with a Luer-lock fitting for connection with an inflation device.

RX Performance History	TREK and MINI TREK RX have been released into commercialization in the European Union; however, complaint data is limited and will not be analyzed in this report. **Customer Complaint Summary for RX** VOYAGER™ CDC: VOYAGER™ RX CDC data was compiled through the VIPER Complaint Handling System from January 1, 2008 to May 31, 2010 and used for the following analysis. The overall complaint rated is calculated by dividing the total number of reported complaints by the total number of units sold. The Top Complaint rates are calculated (b)(4) [redacted]

[1] Note: 369 of the reportable incidents were associated with a S-1 severity (either patient code 2199 – No consequences or impact to patient or 2648 – No patient involvement). These incidents will not be included in the RX™ Voyager CDC Reportable Incidents analysis below.

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RX Performance History (continued)	(b)(4) [redacted]
	CDC was Failure to Advance. However, there were no reportable incidents related to Failure to Advance. The TREK RX catheter is designed for cross, track and push, which are all performance characteristics that affect the physician's ability to advance the catheter in the patient's anatomy. Cross will be improved by reducing the profile of the tip, distal balloon seal and folded balloon, as well as by the application of a second coat of hydrophilic coating, improving the coating durability. Track will be improved by utilizing a new tip design and coating the inner diameter of the inner member. Finally, inner member/outer member combinations of material and configuration were chosen to optimize the push efficiency and flexibility of the catheter. A number of steps have been taken to reduce the number of balloon ruptures experienced with the TREK RX balloon as compared to VOYAGER™ RX CDC. The 2.25-5.0 balloon sizes utilize a co-extruded Pebax material as well as are blown via a double blow process. Bench testing of the TREK RX balloons will be more rigorous than the testing performed on VOYAGER™ RX CDC as

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RX Performance History (continued)	new STMs have been implemented for balloon fatigue and balloon in-stent rupture. These new STMs were designed to more closely mimic the operational procedures under which the catheter is used in the field, per the IFU. Finally, decreasing the balloon profile will reduce the amount of interaction between the balloon and the Guide Catheter and/or anatomy, which weakens the balloon and makes it more prone to rupture. Kinks were the third most commonly observed complaint with VOYAGER™ RX CDC and go hand in hand with the difficult to position incidents. The majority (>95%) of the difficult position incidents were related to resistance between the device and the guidewire and resistance between the device and the guide catheter. This resistance causes the catheter to kink in many cases. The TREK design features that will address these complaints are decrease in catheter profile (tip, crossing, and balloon, tip design and IM coating. Additionally, the TREK RX catheter was designed to have a gradual transition of stiffness, from distal to proximal, optimizing both flexibility on the distal end and push transmission for ease of delivery. Additionally, all S-5, patient code 1802 (patient expires) reported incidents were reviewed by engineering. There were two reported incidents and in both incidents, the patient's death was related to the circumstances of the procedure and not product quality issues.

OTW Performance History	**Customer Complaint Summary for** VOYAGER™ OTW CDC: VOYAGER™ OTW CDC data was compiled through the VIPER Complaint Handling System from January 1, 2008 to May 31, 2010 and used for the following analysis. The overall complaint rated is calculated by dividing the total number of reported complaints by the total number of units sold. The Top Complaint rates are (b)(4) [redacted]

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OTW Performance History (continued)	(b)(4) [redacted]
	Just like with VOYAGER™ RX, the highest number of reported incidents with the VOYAGER™ OTW CDC was Failure to Advance. There were no reportable incidents related to Failure to Advance. The TREK OTW catheter is design contains the same performance design features as TREK RX, which addresses the complaints observed for VOYAGER™ OTW. The TREK OTW balloon is identical to the TREK RX balloon and all risk mitigation described above for TREK RX is applicable to TREK OTW. Difficult to position was third most commonly observed complaint with VOYAGER™ OTW CDC. All of the reported incidents were related to Guidewire interaction difficulties. The IM coating process has been optimized to reduce GW interaction effects during use of the catheter. There were zero (0) S-5 incidents reported for VOYAGER™ OTW CDC. **FDA Maude Database:** The FDA MAUDE (Manufacturer and User Facility Device Experience) database was reviewed to identify potential failure modes associated with the TREK RX and TREK OTW. The query included searches for reportable incidents resulting in death or

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Performance History (continued)	(b)(4) [redacted]

Risk Charts	Occurrence rates used in the Phase I Risk Assessment worksheet for device-related hazards and effects, for same design and material components, were based on occurrence (Phase III) rates of the predicate device. Occurrence rates for hazards related to the operational context of the device and operator processing error were also based on predicate device complaint/NCMR data. For design components (dimensions, equipment or construction) and material components that are significantly different from the predicate, a worst-case O-5 occurrence level was assigned during Phase I. Occurrence rates used in the Phase II and Phase III Risk Assessment are assigned based on the data results from the Process development work, online Reliability Engineering Data, Filing data, Aging data, Process Qualification data and using the occurrence scales listed in DOP678. The occurrence rates are estimated by dividing the number of failures observed, by the total number of units tested. Risk charts were created for each FMEA for both device platforms individually, as well as the line items that affect both device platforms, reference Appendix B. An overall risk chart, combining Line Items from all four FMEAs were created and are shown in Appendix C.

Assessment and Conclusions TREK RX	The results of the completed TREK RX Risk Assessment, as summarized in the risk charts, demonstrate that there are no remaining HIGH risk items (as defined per DOP678). There are 104 items identified with a residual risk level of MEDIUM after application of design, process and use error mitigations. Of these, 35 are use related. Appropriate warnings, cautions and other guidance is provided in the IFU. Given the circumstances associated with PTCA, it is not likely to assume that the user may heed all warnings in every case; however the physician is expected to act in the best interest of the patient to achieve the desired outcome. Therefore, these risks are justified, when weighed against alternative treatments available.

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Assessment and Conclusions TREK RX (continued)	The remainder of the items identified with a residual risk level of medium are associated with the design and manufacture of the device. While appropriate mitigations have been applied for each hazard, the probability of each hazard being mitigated to zero is unlikely, therefore the O-2 occurrence rating is applied. The rate at which these hazards may occur is expected to be extremely low and similar to the predicate devices which have demonstrated acceptable complaint rates. Given the benefits of PTCA over alternative treatments and the low occurrence rates for these hazards, the medium risks are considered acceptable. All RAM line items associated with a severity rating of S-3 or higher also carry the potential to result in additional surgical or non-surgical treatment. Examples of Surgical Treatment include, but are not limited to, bypass, intubation, IABP, pericardiocentesis. Examples of Non-Surgical Treatment include, but are not limited to, Snaring, Medication, Additional Ballooning or Stenting. Based on the results of the Phase III assessment, peer reviews design/process improvements, application of risk control measures and comparison to the predicate device's performance, the TREK RX and MINI TREK RX CDC are considered acceptable for clinical use.

Assessment and Conclusions TREK OTW	The results of the completed TREK OTW Risk Assessment, as summarized in the risk charts, demonstrate that there are no remaining HIGH risk items (as defined per DOP678). There are 98 items identified with a residual risk level of MEDIUM after application of design, process and use error mitigations. Of these, 35 are use related. The rationale for acceptance of these medium risks listed above for TREK RX also applies to TREK OTW. Based on the results of the Phase III assessment, peer reviews design/process improvements, application of risk control measures and comparison to the predicate device's performance, the TREK OTW and MINI TREK OTW CDC are considered acceptable for clinical use.

Attachments	Appendix A: Risk Analysis Worksheets (DFMEA, PFMEA, UFMEA, CFMEA) Appendix B: Risk Charts (DFMEA, PFMEA, UFMEA, CFMEA) Appendix C: Overall Risk Charts (RX only, RX & OTW, OTW only)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Risk Analysis Design

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Final: myb 01/10/2011

K103110

cc: WO 66 DMC
WO 66 510(k) Staff
WO 66 DCD Division
D.O.

BLDG	Last Name	Date	BLDG	Last Name	Date	BLDG	Last Name	Date
WO66	Peksta for Boam	1/10/11						
WO DCD	Dreohmes	1/10/11						
WO	GMB22							

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Boilerplate Last Updated: 6/18/09 – Brandi Stuart

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

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http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table

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Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DCD/ICDB	Tatel	12/1/10			
DCD/ICDB	Boa	12/1/10			

Re: K103110
Abbott Vascular Inc.
Trade Name: MINI TREK RX, TREK RX, MINI TREK OTW, and TREK OTW Dilation Catheter

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table in footer
8/25/09	Brandi Stuart	Updated Title of Boiler
8/29/09	Brandi Stuart	Updated Websites
12/2/09	Diane Garcia	Removed Least Burdensome Language
1/21/10	Diane Garcia	Updated web address for 510k actions

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COVER SHEET MEMORANDUM

From: Reviewer Name Katharine Frankak ICDS/DCD

Subject: 510(k) Number K103110/S001

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	Class*	Product Code
21 CFR 870.5100	Class II	LOX

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: L. Peters for A. Beam (Branch Chief) — ICDB (Branch Code) — 1/10/11 (Date)

Final Review: Donna R. VanMeter (Division Director) — BDZ — 1/10/11 (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Premarket Notification [510(k)] Review
Traditional/Abbreviated

K103110/S001

Date: January 7, 2011
To: The Record
From: Katharine Fronczak, MS

Office: ODE
Division: DCD/ICDB

510(k) Holder: Abbott Vascular
Device Name: Mini TREK RX, TREK RX, Mini TREK OTW, and TREK OTW Dilation Catheter
Contact: Suzanne Redman
Principal Regulatory Affairs Associate
Abbott Vascular Inc.
26531 Ynez Road
Temecula, CA 92591
Phone: (951) 914-3243
Fax: (951) 914-0339
Email: suzanne.redman@av.abbott.com

Note: The original review of this 510(k) submission was performed by Dr. Erica Takai. Below is Dr. Takai's complete memo for the original submission. I am the lead reviewer of Supplement 1, the response to our December 2, 2010 additional information letter. See Supplement S001 below for the deficiencies, Sponsor's Response and reviewer comments.

Review Team:
- Jennifer Goode, DCD/PVDB, Biocompatibility Reviewer (mainly for colorant issues)
- Hoan My Do Luu, OSEL/DCMS, Chemist (for colorant elution issues)
- Rosalie Elespuru, OSEL/DB, Toxicologist (for colorant risk assessment)
- Erica Takai, DCD/ICDB, Lead Reviewer (previous PMA and original 510(k))
- Katharine Fronczak, DCD/ICDB, Lead Reviewer (S001)

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Abbott TREK and Mini TREK Rapid Exchange (RX) and Over-the-Wire (OTW) Dilation Catheters into interstate commerce.

This 510(k) was originally a PMA supplement (P810046/S235; see memo for details), which was down classified to a class II 510(k) on October 8, 2010. The Sponsor responded to a major deficiency letter sent August 9, 2010. The current submission is a response to an additional information letter that was sent on December 2, 2010. There are no outstanding deficiencies at this time. We have collected all the information from the MAF colorant holders and there are no outstanding biocompatibility (including color additives information) questions. The Sponsor also adequately responded to our concerns regarding their bench testing. **Therefore, I am recommending a Substantial Equivalence (SE) decision.**

The administrative documents required for a 510(k) were provided via email (11/9/10) and were enclosed in the original 510(k) review. On December 13, 2010 Abbott send me the Standards forms (FDA 3654) that was not included in the original November 9, 2010 email. Email correspondence and forms enclosed.

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II. Administrative Requirements

	Yes	No/ Inadequate	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Summary Elements per 807.92			
(1) Submitter's name, address, telephone number, contact person and date	X		
(2) Name of the device including trade or proprietary name if applicable, the common or usual name, and the classification name if known.	X		
(3) Legally marketed predicate device	X		
(4) Device description	X		
(5) A statement of intended use	X		
(6) If the device has the same or different technological characteristics as compared to the predicate device.	X		
(6) An assessment of performance data. (b) (1) non-clinical tests	X		
(6)(b)(2) Assessment of the clinical tests submitted			X
(6)(b)(3) Conclusions drawn from non-clinical and clinical tests that demonstrate that the device is as safe and effective as the predicate device.	X		
Standards Form	X		
Clinical Trials Form	X		X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

NOTE: the sponsor has added the OTW model in the current submission which was not in the original PMA supplement submission. This information is provided in Attachment 20 of the current submission.

The TREK and MINI TREK RX and OTW Coronary Dilatation Catheters have a rapid exchange or over-the-wire co-axial design with a balloon at the distal tip. The balloon segment expands to a known diameter and length at a specific inflation pressure and has two radiopaque markers to aid in positioning the balloon in a stenosis. The co-axial shaft consists of a tubular inner and outer member. The central lumen of the inner member permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides annular space for inflation and deflation

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of the balloon with contrast fluid.

The size matrix is identical for the RX and OTW versions and is as follows:

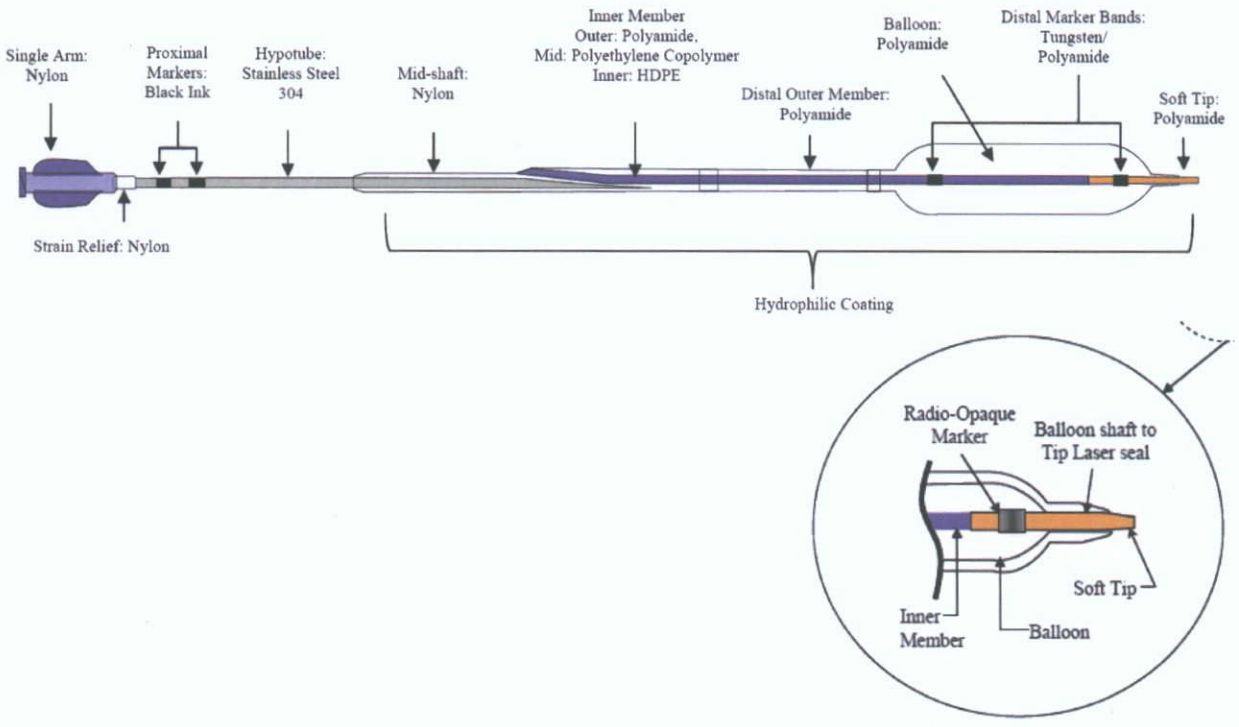
Balloon Diameter (mm)	Balloon Length						
	6mm	8mm	12mm	15mm	20mm	25mm	30mm
MINI TREK OTW Coronary Dilatation Catheter							
1.50	X	X	X	X	X	[redacted]	[redacted]
2.00	X	X	X	X	X	X	X
TREK OTW Coronary Dilatation Catheter							
2.25	X	X	X	X	X	X	X
2.50	X	X	X	X	X	X	X
2.75	X	X	X	X	X	X	X
3.00	X	X	X	X	X	X	X
3.25	X	X	X	X	X	X	X
3.50	X	X	X	X	X	X	X
3.75	X	X	X	X	X	X	X
4.00	X	X	X	X	X	X	X
4.50	[redacted]	[redacted]	X	X	[redacted]	[redacted]	[redacted]
5.00	[redacted]	[redacted]	X	X	[redacted]	[redacted]	[redacted]

The RX catheter is packaged with a primary flushing tool (to perform initial lumen flush using a syringe), protective sheath (on the balloon), dilation catheter clip, and a compliance card. The flushing tool, protective sheath, and dilation catheters are identical to those packaged with the VOYAGER devices. The dilatation catheter clip is intended to be used to coil the catheter when it is not being used but remains on the sterile field or table (to prevent it from falling or dangling and becoming contaminated). The OTW catheter does not include these accessories.

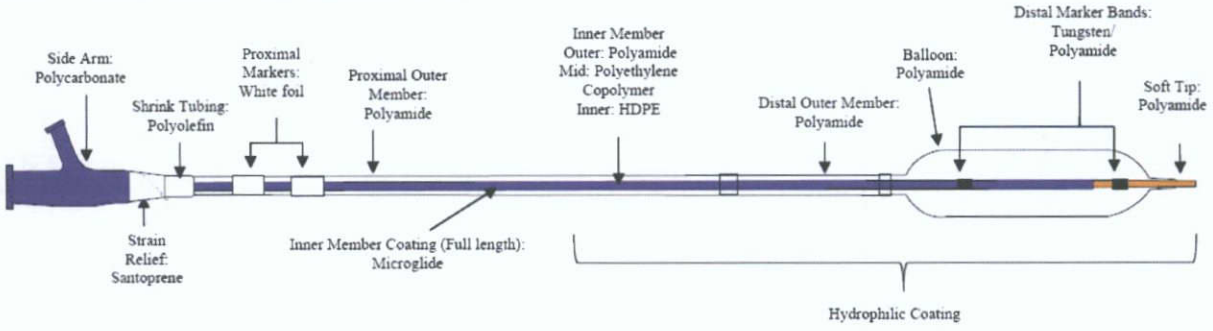
RX Catheter:

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OTW Catheter (distal end identical to RX):



IV. Indications for Use

The indications for use for the TREK™ RX and MINI TREK™ RX Coronary Dilatation Catheters are as follows:

> The TREK™ RX and MINI TREK™ RX Coronary Dilatation Catheters are indicated for: (a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion; (b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction; (c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

The indications are similar to that of the VOYAGER RX Coronary Dilatation Catheter (P810046/S216):

> The VOYAGERTM RX Coronary Dilatation Catheter is indicated for: (a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion, (b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction, (c) balloon dilatation of a stent after implantation. (Testing included the following Guidant stents: MULTI-LINK: PIXEL®, and PENTA® / ZETA® Coronary Stent Systems.)

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The main difference is in the stents identified for post-dilation (balloon size vs identifying specific stents). There are currently no stents (bare or drug eluting) that are indicated for a reference vessel diameter <2.25mm, and the indication states that the post dilation use applies only to 2.0-5.0mm models only. Accordingly, in-stent bench tests (fatigue and burst) were performed on 2.0mm or larger sizes. The indications are acceptable.

V. Predicate Device Comparison

The TREK RX and MINI TREK RX are similar in deign, material and indications to the currently approved VOYAGER RX Coronary Dilatation Catheter (P810046/S216, approved June 18, 2004). The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are similar in design, materials, and indications to the currently approved VOYAGER OTW Coronary Dilatation Catheter (P810046/S214, approved March 12, 2004). Additionally, the distal portion of the catheter from the mid-lap joint to the tip, including all balloon diameters and lengths, is identical to the same distal portion of the TREK RX and MINI TREK RX Coronary Dilatation Catheters.

The new design of the TREK/MINI TREK RX and OTW Coronary Dilatation Catheters include the following:

- A Pebax balloon with a Rated Burst Pressure (RBP) of 14 atm. Pebax 70D is used for the 1.50 mm through 2.00 mm balloons. A co-extrusion of Pebax 70D over Pebax 63D is used for the 2.50 mm through 5.00 mm balloons.
- A single piece hypotube design across all balloon sizes that includes a redesigned guide wire notch. (only RX)
- A tip-through design where the soft tip is directly joined to the inner member under the balloon's distal taper.
- A Microglide coated inner member intended to improve device interaction between the guide wire and the catheter.
- The absence of glue joints. All joints are bonded using methods which do not involved the use of adhesives. (RX only; OTW has adhesives in the proximal bond see 11/24/10 email)

(Comparison table compares items in table to the TREK/Mini-TREK OTW)

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PREDICATE COMPARISON
TREK™ OTW and MINI TREK™ OTW Coronary Dilatation Catheters

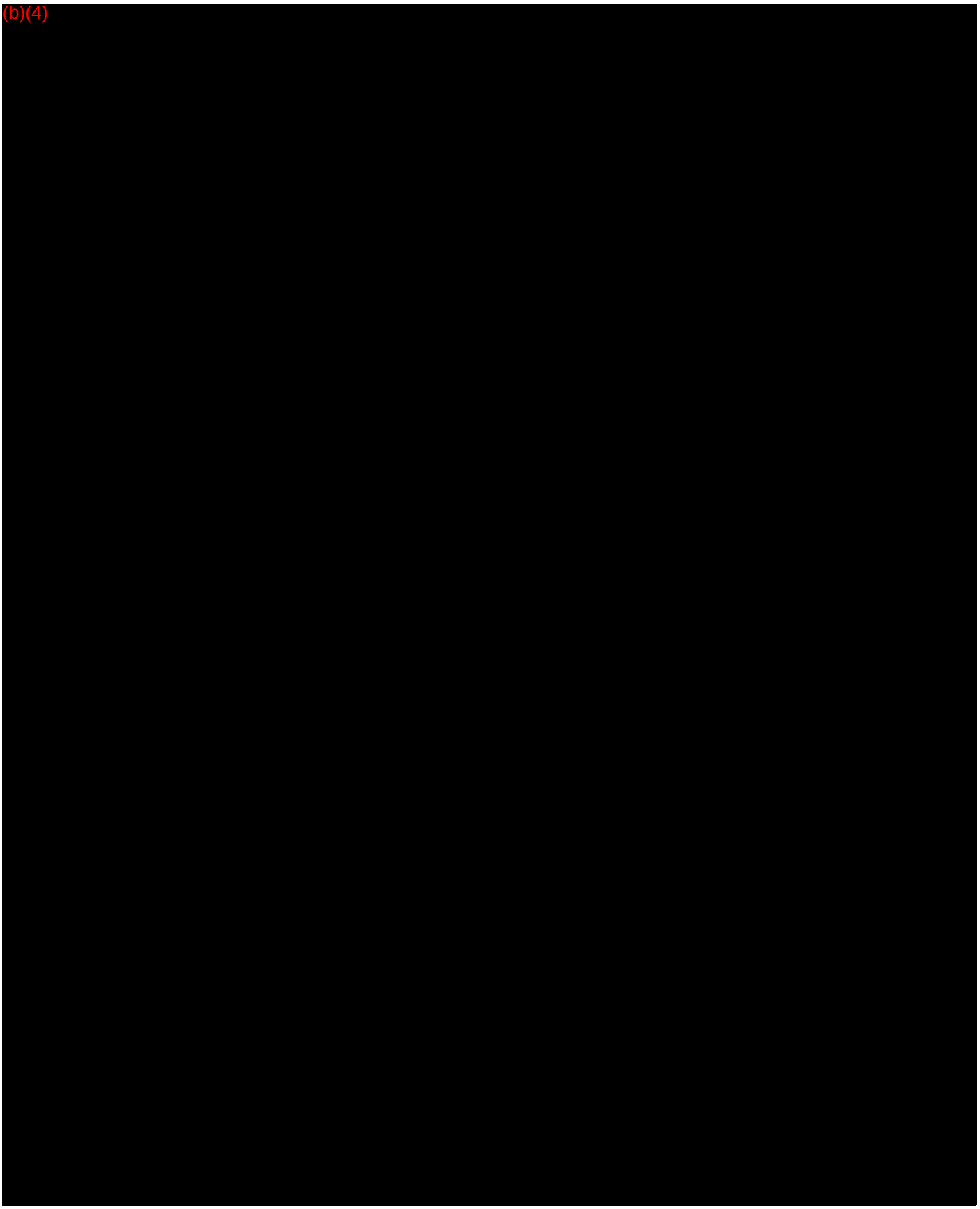
(b)(4)



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(b)(4)



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(b)(4)

[redacted]

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(b)(4)



Although not listed in the materials table above, for the TREK/Mini TREK OTW, the outer member and inner member are bonded to the two-arm adapter (proximal adapter) using Loctite 3201 UV adhesive. Abbott confirms that the TREK and MINI TREK OTW uses the same Loctite 3201 UV curing adhesive at the proximal adaption bond as the VOYAGER OTW. There are no other joints which are attached via adhesives in the TREK and MINI TREK OTW (per 11/24/10 email). No adhesives are used in the RX version.

VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.807.87 (e).

The labeling includes a prescription only symbol, and appropriate warnings regarding single use/not resterilizing or reusing. The labeling also includes a device description and indications statement which are appropriate. They also include a summary of the GUSTO II Direct PTCA Substudy of patients with ST segment elevated myocardial infarctions. This trial did not use the subject PTCA catheter. The directions in the IFU were generally clear and adequate. See deficiencies section below for issues related to missing inflation cycles and Rx symbol missing from the glossary. No compliance chart in IFU though in label.

VII. Sterilization/Shelf Life/Reuse

The same sterilization cycle is performed by the same sterilizer as the VOYAGER RX catheter (P810046/S216). The materials used for the subject catheters are similar (differences primarily in a different formulation of Pebax), and the lumen diameters are similar or larger to the VOYAGER RX. The sterile barrier used for the TREK and MINI TREK, both RX and OTW, are identical to the VOYAGER RX. Due to the similarity between the TREK/MINI TREK and the Voyager in materials, dimensions, and packaging, it is acceptable to leverage sterilization information.

1. Sterilant:	YES	NO

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a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	EtO	
b. **Dose**, for radiation (e.g., 25 – 40 kGy):		NA
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	EtO <0.1mg ECH <0.1mg (per ISO 10993-7)	
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g., ANSI/AAMI/ISO 11135))	Per ISO 11135:1994 (leveraged from P810046/S216)	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	Non-pyrogenic	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	LAL (20EU/device limit) Lot release (See review memo for P810046/S235 for details)	
5. A description of the packaging		

Packaging

After final assembly and testing, the catheter is packaged and sterilized as a single use unit. The product is first inserted into the high density polyethylene coil dispenser. The dispenser coil is then placed into a linear low-density polyethylene/nylon/linear low-density header bag. A compliance chart is also inserted into the header bag. The completed, chipboard boxed product is shipped to the customer in corrugated boxes designed to protect the finished product from damage in transit. During the packaging operation, each lot of product is 100% inspected by the operator and audited by Quality Control (QC) for final seal integrity, label accuracy, and particulate contamination.

The following packaging tests were provided at baseline and after 3 year accelerated aging:

- Visual Inspection
- Pouch Seal Strength (n=30 each from 3 lots, and from 3 sealers)
- Bubble Leak Test (n=59) and Seal Strength after drying from the bubble leak test

(b)(4) [redacted]

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It appears that a room temperature of 20˚C was used in this calculation. If a more conservative 25˚C was used for room temperature, 3 years would be 97 days (and the current 68.5days would be equivalent to about 2.1 yrs). See deficiency section below regarding the 20C RT use.

Shelf Life

Samples were accelerated aged at 55˚C, 20% relative humidity (RH), and calculated accelerated aging based on a 20˚C room temperature. See deficiency section below regarding the use of 20˚C RT (they have adjusted their claimed shelf life.

The sponsor is claiming a 6-mo shelf life for the TREK/Mini-TREK OTW and 1 year for the RX (confirmed via email 11/24/10). See bench testing section for functional shelf life testing.

VIII. Biocompatibility

See review memo for P810046/S235 for details on biocompatibility testing for the RX. See deficiency section below for concerns identified previously.

Testing previously provided for the RX include:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis (direct and indirect/extract)
- Complement Activation
- In vivo Thrombogenicity (not performed but acceptable rationale provided)

(b)(4) Testing

[redacted]

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(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

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Deficiency:

2. In your Soft Tip to Inner Member Tensile test for the OTW TREK catheters, it appears that the 2.25 x 30mm size experienced a significant decrease in tensile strength between baseline and 6 months. Please provide a statistical comparison of aged and baseline results, and provide a scientific or clinical justification for why you believe a significant decrease in tensile strength with aging does not raise a safety concern. Please acknowledge that for future submissions, you will provide statistical comparisons for performance tests with quantitative metrics to demonstrate whether a significant negative effect on performance was observed post-aging. In addition, please acknowledge that you will not extend your shelf life if any of your devices do not meet the acceptance criteria set at baseline, for all of your tests.

(b)(4) Testing

[redacted]

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XIII. Performance Testing – Clinical

Response to Deficiencies

Question 1. You have performed biocompatibility testing on Mini TREK devices but not the TREK devices. To justify this, you stated that the Pebax 70D / Pebax 63D co-extruded balloons used in the TREK devices are identical in materials and subjected to the identical type of manufacturing processes as the balloons for the VOYAGER® NC Coronary Dilatation Catheters Catheter (P810046/S226). However, the soft tip, and inner and outer member materials to which the balloon is fused onto are different from the TREK and VOYAGER devices, and it is unclear whether this manufacturing step with different combination of materials may alter the biocompatibility of the final device. Please perform biocompatibility testing on final sterilized TREK devices or provide additional justification on why you believe the combination of different balloon, soft tip, and inner and outer member materials would not affect biocompatibility. This may be achieved through comparison of extracts (polar, non-polar, and MEM used for cytotoxicity testing) of the distal catheter segment, which includes part of the distal shaft and balloon, for the TREK and MINI TREK to demonstrate that the chemical leachants are the same.

Sponsor Response:
The sponsor clarifies that the TREK RX balloon has a Pebax 63D inner layer under the balloon's Pebax 70D outer layer. The MINI TREK RX does not have a separate inner layer and is comprised solely of the Pebax 70D material which is used for the TREK RX balloon outer layer. Pebax 63D is also present on both the TREK RX and MINI TREK RX as the inside layer of the distal outer member, and is, therefore, included as part of the device chosen for biocompatibility testing

With respect to the laser processing of the soft tip, and inner and outer member materials to which the balloon is fused, Pebax is a polyether block amide copolymer manufactured by Arkema, with 70D or 63D referring to Shore D durometer. Pebax 63D and Pebax 70D are comprised of polyamide blocks and polyether blocks. Pebax 63D has a higher polyether block content which makes it a lower durometer. The laser bonding process used to bond the balloon to the catheter heats the Pebax balloon to temperatures above the melting point. Melting temperatures of Pebax 70D and 63D are 172oC and 169oC, respectively. During the melting, a blend of the polyether and the polyamide is created. In the case of the 63D/72D joint vs. the 70D/72D joint, there is a slightly higher amount of polyether and a slightly lower amount of polyamide. Due to the mixing effect that occurs during the melting, the constituents in the catheter remain unchanged regardless of the durometer. Therefore, the distal and proximal laser processes of two balloons with different durometers of the same materials are considered identical and do not present additional questions related to biocompatibility.

Reviewer Comments: This justification for why biocompatibility testing can be leveraged from the Mini TREK RX to the TREK RX, where there is a combination of different durometer Pebax in the TREK RX balloon than in the mini TREK RX, and the same 63D Pebax in the TREK RX balloon is also used in the mini TREK RX distal outer member, is **acceptable**.

Note that new biocompatibility testing was performed for OTW devices due to the differences in the proximal end of the catheter compared to the RX devices (see biocompatibility section above).

Question 2. In your biocompatibility test reports from Pacific BioLabs, the test article was identified as 'Xcalibur RX' and as a "delivery system, needle, and a clamp." In your July 29, 2010 email, you clarified that a needle is not part of the TREK or MINI TREK device. Furthermore, the clamp, which appears to refer to the dilation catheter clip, is not a patient contacting portion of the device, as it is used to keep the catheter coiled when not in use. Therefore, extracts used in the tests performed by Pacific BioLabs (cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, and material mediated pyrogenicity) included inappropriate materials, not representative of the patient contacting portions of your final device. Inclusion of these other materials may lead to a relative dilution of chemical leachants from your device, making the biocompatibility testing results uninterpretable. Please repeat testing using just the TREK or MINI TREK catheter alone, and provide a complete test report. Alternatively, please provide a justification for including these other materials in your test extract, and why you believe the inclusion of

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these other materials would not affect the outcome of your test results.

Sponsor Response: The sponsor clarified that the needle is actually the flushing tool, and both this and the clamp have indirect patient contact.

In an email (9/29/10) regarding the same deficiency sent for the Mini Trek IDE G100141 (smaller balloon size), the sponsor has provided the following additional information:

Table 1 Tests Performed by Nelson Laboratories

	Surface Area of the FLUSHING TOOL (cm^2)	**Percentage of the FLUSHING TOOL Compared to the Catheter**	**Surface Area of the CATHETER CLIP (cm^2)**	**Percentage of the CATHETER CLIP Compared to the Catheter**
	5.0	9.2%	7.7	14.2%
Ratio used in the test extract for Indirect Hemolysis	$3cm^2/1mL$ [a]		$3cm^2/1mL$ [a]	
Ratio used in the test extract for Direct Hemolysis	$3cm^2/1mL$ [a]		$6cm^2/1mL$ [a]	
Ratio used in the test extract for Complement Activation	$3cm^2/1mL$ [a]		$3cm^2/1mL$ [a]	

Total surface area of the catheter (cm^2) = 54.1

[a] *The ratio is based on the volume from the flushing tool or catheter clip to the total volume of extract fluid, blood or serum. The values are approximates within ± 10%.*

They also clarified via email that the entire device including the clip and flushing tool were used for biocompatibility extractions except for complement activation (direct contact) and that the relative surface area ratios for the clip and flushing tool to the rest of the catheter were maintained when preparing these extracts. This only applies to the RX as OTW did not include the clip or flushing tool. This was confirmed via email (11/24/10). The sponsor also confirmed this information provided (via email 9/29/10) in reference to G100141 is applicable to the current submission.

Reviewer Comments: Given that there is indirect contact of these accessory components, the relatively smaller surface area of the accessories in relation to the device as a whole, and the fact that the materials themselves are not novel, this is **acceptable**. Note that this topic was discussed with Ms. Goode, who also agreed.

Question 3. For all biocompatibility tests, please clarify whether the extracts were filtered or otherwise manipulated after they were prepared. Please note that this information should be included in your final test reports.

Sponsor Response/Reviewer Comments: For all biocompatibility tests, the extracts prepared from the test article were not filtered or otherwise manipulated after they were prepared. Sponsor also states this is true of biocompatibility tests provided for the OTW device in Attachment 20. *This response is **acceptable**.*

Question 4. For cytotoxicity testing, please clarify how long after preparation the extracts were used.

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Sponsor Response/Reviewer Comments: The sponsor states that according to Pacific BioLabs, based on the raw data, cytotoxicity testing of the test article extracts occurred within 11 minutes after the incubation. They also state that for testing on OTW devices in Attachment 20, NAMSA states that extracts were used within 27 min after extraction. *This response is* ***acceptable***.

Question 5. Please address the following concerns regarding both your direct contact and extract hemolysis tests:
a. Please provide a more detailed description of the test article. The test article was only identified as 'Xcalibur RX.' For the direct contact test, please clarify what portion of the device was used and provide a justification for the portion used.
b. Please clarify whether blood from only one human donor was used or if multiple donors were pooled.
c. For the extract test, please clarify how long the extract was stored before use.
d. Please clarify the plasma free hemoglobin value of the blood sample used.

Note: sponsor states that these responses also apply to the OTW testing in Appendix 20 unless otherwise noted.

Sponsor Response/Reviewer Comments:
a. Sponsor states that the test article identified as "Xcalibur RX" was composed of the delivery system, along with the flushing tool and catheter clip, referred to as "needle" and "clamp" respectively in the biocompatibility reports (Xcalibur RX was the project name for the TREK/Mini TREK). The total surface area of all components of the device was calculated to be 73.3 cm^2. Each component of the test article was divided into approximately three parts, where each part was added to a separate tube, for a total surface area of approximately 24 cm^2 per tube. Note that the flushing tool and catheter clip are not included with the TREK OTW and MINI TREK OTW and were, therefore, not included as part of the test article for hemolysis testing. *Extraction was 3cm^2/mL. This response is* ***acceptable***.

b. Sponsor states that human blood from one donor was used. This is acceptable given that the NIH method does not require multiple donors, and materials used were not novel. This response is **acceptable**.

c. Sponsor states extracts were used within 1 hr after removal from the incubator. This response is **acceptable**.

d. Sponsor states that the plasma free hemoglobin value for the direct contact hemolysis test was 0.541 mg/mL, and for the extract hemolysis test the PFH was 0.325 mg/mL. These values are <2.0mg/mL. This response is **acceptable**.

Question 6. For your complement activation testing, please provide a more detailed description of the test article, since the test article was only identified as 'Xcalibur RX.' Also, since it appears portions of the device was used to incubate in serum, please clarify which portions were used and why you believe the portions used were representative of the entire patient contacting portion of your device.

Sponsor Response/Reviewer Comments:
Sponsor states that per Nelson Laboratories, the test article identified as "Xcalibur RX" (project name for the TREK/Mini TREK) was composed of the delivery system, along with the flushing tool and catheter clip, referred to as "needle" and "clamp" respectively in the biocompatibility reports. The total surface area of all components of the device was calculated to be 69.5cm^2. Each of the twenty one (21) components of the device was divided by 21, where approximately 1/21 of each component was included into each test tube, for a total surface area of 3.3 cm^2 per tube. Extraction was 3cm^2/mL. Note that the flushing tool and catheter clip are not included with the TREK OTW and MINI TREK OTW and were, therefore, not included as part of the test article for complement activation testing. This response is **acceptable**.

Question 7. Please provide the following information regarding all color additives used in your device (with the exception of violet colorant used in the arm adapter, which is non-patient contacting):
a. Chemical name and Chemical Abstract Services (CAS) number;

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b. CFR sections to which the color additives comply (with clarification on whether the color additive as used in the device conforms to the CFR for amounts, dye specifications, etc.);

c. Certification that color additive is from a batch that does not need to be certified in accordance with regulations issued under 706(c) for that use (i.e., colors not requiring certifications are listed under 21 CFR 73 (Subpart D)). Color additives not exempt from the certification requirement are listed under 21 CFR 74 (Subpart D);

d. Specific amount of each color additive in the formulation by weight percent of the colored component and total amount (e.g., µg, ppm) in the device;

e. Material Safety Data Sheets (MSDSs) for each color additive;

f. A risk assessment for each color additive, using toxicity information from the literature to include NOAEL, LOAEL, LD50, type of animal model, route of exposure, etc.

g. Data to demonstrate the amount of color additive eluted from the device over 30 days (or appropriate clinical worst case exposure plus a safety margin), to include:

i. Justification for the extraction solvents (which will be dependent on the chemical nature of the color and the polymer matrix);

ii. Justification for the sensitivity of the study (i.e., detectable levels) to include spiking and recovery assessments to confirm that test is capable of detecting the presence of the color additive in the test system; and

iii. Justification for the allowable levels eluted to include calculation of patient exposure. If repeat dosing is possible or probable, this should be considered in the patient exposure calculation.

h. If the color additive "leaches" or elutes from the device, further assessments of the fate of the color additive in a relevant animal model (to include the timing of elimination, i.e., animal model evaluation as the product is intended to be used with pharmacokinetic type of analysis, ADME study); and

i. If the color additive remains in the animal for greater than 30 days, then a CFSAN review of a color additive petition (CAP) would be necessary.

Sponsor Response/Reviewer Comments:

NOTE: Abbott has submitted the same information for the MINI TREK 1.2mm devices in G100141/S2 and additional information in S/7. Dr. Luu and Ms. Goode have provided consulting reviews on these information, which are briefly summarized below (see Dr. Luu's consult email and Ms. Goode's memos attached)

a. Chemical name and CAS numbers:

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(b) (4)

[redacted]

This response is **acceptable**.

b &c. CFR listings:
Sponsor provided the requested information for part b, but for the exemption from batch certification per CFR (part c), Bayer and CFC have not responded and a request for this information was sent to the *MAF* holders via email (see Ms. Goode's 11/30/10 memo for details)

d. Amounts:
Sponsor/MAF holders provided this information (see Ms. Goode's 11/30/10 memo for details). This response is **acceptable**.

e. MSDS:
Some were still missing from CFC's white foil and a request for this information was sent to the MAF holders via email. (see Ms. Goode's 11/30/10 memo for details).

f. Risk Assessment:
Both Dr. Hoan My-Do Luu, and Dr. Rosalie Elespuru reviewed this colorant information and risk assessment. While Dr. *Elespuru did not agree with all* of the scientific statements made by Abbott Vascular in this risk assessment, she and Dr. Luu both agreed that additional information regarding these colorants (from a toxicity perspective) are not needed. Dr. Luu also reviewed the Table A6-5 regarding solubility of the various chemicals, and agreed that the risk of leaching is minimal. Ms. Goode indicated in her memo (11/30/10) that this response is **acceptable**.

g-i. Leaching study, CAP etc
These are not applicable/needed based on the risk assessment being acceptable (part f).

Deficiency:

3. For the colorant being used in the white foil proximal marker, please acknowledge your understanding that additional information is being requested of CFC International regarding their Type III DMF #17442 letter of authorization dated August 27, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

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4. For the aqua colorant being used in the RX Catheter Clip, please acknowledge your understanding that additional information is being requested of Clariant regarding their Type III DMF #10640 letter of authorization dated September 10, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

5. For the colorant being used in the purple colorant used in the side arm, please acknowledge your understanding that additional information is being requested of CFC International regarding their MAF#0353 letter of authorization dated August 26, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

Question 8. For nearly all bench tests performed, it was not clear how you determined the sample size needed for each test. For all bench tests, please clarify how you determined the sample size. For example, the number of samples tested for rated burst pressure should demonstrate 95% confidence and 99.9% reliability that the balloons will survive. If you determine that an insufficient number of samples were tested, please test additional samples. Please refer to our draft guidance Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters for more details regarding sample size recommendations for each test.
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070984.htm

Sponsor Response/ Reviewer Comments:
The sponsor states that sample size was determined based on one of 2 methods:

Statistical Rationale
- Rated Burst Pressure (RBP) – 95% confidence and 99.9% reliability (n=20 at t=0 and n=15 at 2 yrs per size)
- Minimum Balloon Burst Strength (In Stent) – 95% confidence and 99.9% reliability (n=20 at t=0 and n=15 at 2 yrs per size)
- Balloon Compliance Pressure– 95% confidence and 99.9% reliability (n=19 or 20 at t=0 and n=14 or 16 at 2 yrs)
- Balloon Fatigue– 95% confidence and 90% reliability (n=30)
- Balloon Fatigue (in stent)– 95% confidence and 90% reliability (n=30)

Scientific Rationale:
"For all remaining bench test performed, the number of samples was based on the acceptance criteria required to demonstrate that the design meets dimensional and functional specifications per the product specification. For these tests, the minimum sample size was selected based on requirements described in AV's internal operating procedure for Filing and Aging Testing which specifies a minimum sample size of 10 units per test group."

Using a six sigma approach (process capability to produce outputs within specification limits or Cpk), the sponsor set Cpk ≥ 1 which gives a reliability of ~≥ 99% for one-sided specifications, 95% confidence interval (alpha 0.05), and a 90/90 confidence and reliability and calculated n=9 for with these parameters. *The calculation provided appears to be correct, although it appears that the industry standard for six sigma approach is n=30 (and anything lower may be justified by Cpk analysis).*

This response is ***acceptable****.*

Question 9. In your Catheter Preparation test, it is not clear why you did not include the 4.0mm x 30mm size device for both baseline and aged device testing, since it is one of the largest diameter balloons with the longest length. In addition, it is unclear why you have tested a different size TREK RX device for your aged samples and baseline (un-aged) samples. Please repeat testing on aged 5.00mm x 15mm devices and on both aged and baseline 4.0mm x 30mm size devices, and provide a complete test report. Alternatively, please provide a scientific rationale for the device sizes tested.

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Sponsor Response: The sponsor clarifies that the balloon size does not affect the ability to prep the device because the balloon is held under negative pressure, effectively eliminating any volume of air within the balloon (prior to prep). The catheter shaft is identical across all balloon sizes, for TREK RX and MINI TREK RX. The catheter shaft internal dimensions affect the ability for the contrast to flow through the inter-lumen space during prep. One size balloon from each chassis configuration, for both baseline and aged samples, were tested to represent all sizes in the matrix.

Reviewer Comments: Given that other tests (crossing profile, inflation/deflation etc) assess related characteristics, this response is **acceptable**.

Question 10. In your Catheter Profile test, it appears you did not perform the Crossing Profile test on 4.0mm x 30mm size devices at baseline and after aging, although you have performed Refolded Profile testing on this device size. Please perform Crossing Profile testing on 4.0mm x 30mm size devices at baseline and after aging, or provide a scientific rationale for the omission of this device size. Similarly, it is unclear why the 2.00mm x 30mm size device, which is the largest diameter and longest balloon length MINI TREK device, was not subjected to Refold Profile testing after aging. Please perform Refold Profile testing on the 2.00mm x 30mm size devices and provide a complete test report, or provide a scientific rationale for the omission of testing using this device size.

Sponsor Response/ Reviewer Comments:
Sponsor states that the Crossing Profile was tested on the 5.00 mm x 15 mm balloon diameter for both the baseline and aging as it is the largest diameter and represents the largest crossing profile specification within the TREK RX product family. The product specification requirement for crossing profile on the 5.00 mm size is 0.048" maximum, and the sponsor states their label claims for 5F guide catheter compatibility based on 0.056" ID minimum guide catheters. Therefore, the 5.00 mm x 15 mm size is considered to bracket all sizes within the product family, including the 4.00 mm x 30 mm balloon diameter. *The sponsor only states "Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery" in their IFU and are not limiting to 5F guide catheters.*

Sponsor states that for aged devices, Refolded Balloon Profile was tested on the 4.00 mm x 30 mm and 5.00 mm x 15 mm because the 5.00 mm is the largest diameter that must be capable of pullback into a 6F guide catheter (15 mm balloon length is the longest balloon length available for the 5.00 mm balloon diameter) and the 4.00 mm balloon diameter is the largest diameter that must be capable of pullback into a 5F guide catheter. These were identified to therefore be the worst case. *Given that the refold profile is not a required test, and simulated use testing was performed as part of particulates testing, this portion of the response is* ***acceptable****.*

Deficiency:

6. In your response to deficiency #10 of our August 9, 2010 letter (P810046/S235) regarding Crossing Profile, you indicate that your label claims compatibility with 5F guide catheters based on a 0.056" ID minimum for these guide catheters. However, your IFU currently only states "Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery" and are not limiting compatible accessories to 5F guide catheters. The labeling language regarding guide catheter selection is acceptable since you have identified the French size of the thickest part of each device size in your labeling (3.4Fr for all devices). However, it is unclear whether your testing sufficiently assesses the compatibility of the guide catheters expected to be used. Specifically, in response to deficiency #17f regarding Particulates testing (combined with simulated use testing), you have identified the accessory devices used in your testing but did not specify the accessory device sizes. Please provide this information.

Question 11. The rationale behind the device sizes selected for post-aged Balloon Fatigue testing was not clear. Please repeat Balloon Fatigue using aged samples of all "corner sizes" for both the MINI TREK and TREK catheters or provide a scientific justification for the sizes used for post-aged samples. Specifically, the 2.75mm x 30mm size does not appear to be a corner size, and this 2.75mm x 30mm size was not tested at baseline.

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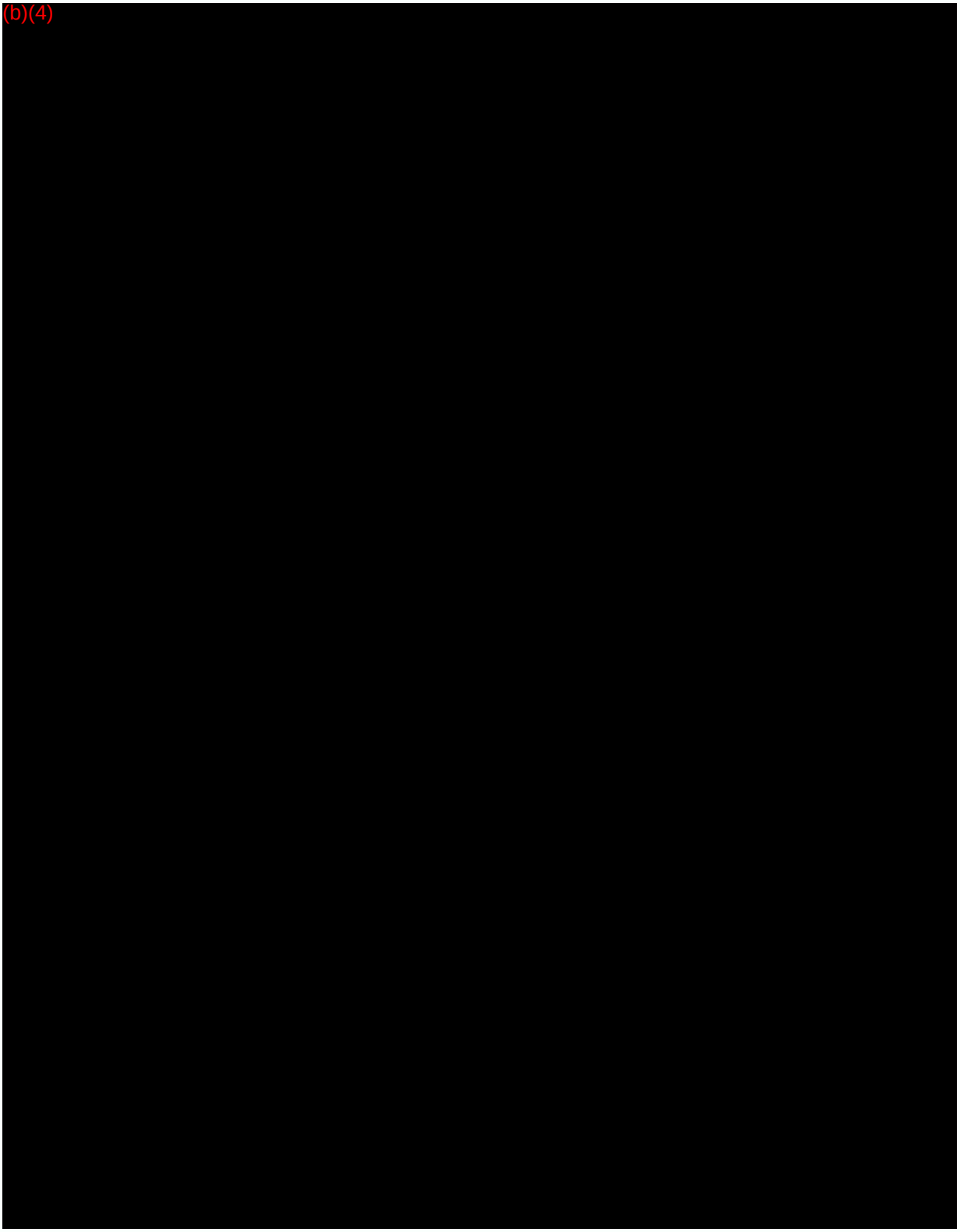
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Sponsor Response:
The sponsor states that they performed baseline testing on all corner sizes for the TREK and MINI TREK, and provide the following rationale for choosing non corner sizes. They performed an engineering study to identify and select the post-aged sizes to be tested for balloon outputs to identify actual worst-case balloon diameters for each balloon design, MINI TREK (single layer, 1.50 mm – 2.00 mm) and TREK (co-extruded, 2.25 mm – 5.00 mm), to be tested for post-aged balloon outputs. This study evaluated balloon fatigue and balloon rupture for the shortest and longest lengths of each balloon diameter at baseline (clarified in 11/24/10 email). The shortest and longest lengths within each diameter were pooled for analysis. A minimum of 30 samples per diameter were evaluated.
From 11/24/10 email:

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(b)(4)



Sponsor states that while each size met all specifications, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters.

Reviewer Comments: The sponsor used 1.50 mm x 20 mm (Mini TREK, also tested at baseline) and 2.75 mm x 30 mm (TREK, not tested at baseline) for their aged device testing. In their engineering study to ID

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the worst case device for aging testing, the sponsor did perform balloon fatigue testing to 20 cycles for the 2.75x30mm size at baseline, and all samples passed. However, from this engineering study and the Balloon Rupture test provided in the P810046/S235, it is not clear that the 2.75 size is worse than the 5.0mm size devices.

Deficiency:

7. Please address the following concerns regarding the lack of testing using the 5.0x15mm device size for Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing:
    a. You have performed an engineering study using baseline samples to identify the worst case device size for the TREK and Mini TREK catheters (RPT2073031), which examined Balloon Fatigue (without a stent) and Balloon Rupture. It is unclear from this test report whether the 2.75mm balloon is indeed the worst case when compared to the 5.0mm balloons, in part because the data from the shortest (6mm) and longest (30mm) were pooled. You have also provided Balloon Rupture testing using devices determined to be worst case from your initial engineering study (p. 6-72 of P810046/S235). From the test data provided in your P810046/S235 submission, the 5.0x15mm and 5.0x12mm size devices had the lowest Rupture pressure and RBP at baseline, lower than that of the 2.75x30mm devices. Therefore, from the data presented, it is unclear whether the 2.75x30mm diameter devices used for post-aged testing is the worst case compared to one of the 5.0mm diameter devices. Please perform Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing on your worst case 5.0mm device size aged to your proposed shelf life, or provide additional data to support the 2.75x30 mm size as the worst case.
    b. You also noted in response to deficiency #13 regarding Balloon Rupture testing, that the data from the baseline 5.0x15mm devices give the appearance that this is the worst case size, but attribute this to lot-to-lot manufacturing variations. Since it appears that you have not perform Balloon Rupture testing on different lots for a given device size, we cannot conclude that differences observed between different sizes are due to different lots and not due to the device size. Please keep this in mind, should you chose to provide additional justification for testing the 2.75x30mm devices post-aging.

Question 12. Please address the following concerns regarding your Balloon Fatigue Within a Stent testing:

a. You did not perform this test using the 1.50mm x 6mm size (smallest diameter x shortest length) device at baseline or post-aging. Please repeat testing using 1.50mm x 6 mm size devices and provide a complete test report, or provide a scientific rationale for the omission of testing using this device size.

b. Please repeat testing using aged samples of all "corner sizes" for both the MINI TREK and TREK catheters or provide a scientific justification for the sizes used for post-aged samples. Specifically, the 2.75mm x 30mm size does not appear to be a corner size, and this size was not tested at baseline. While you state that "the size selection for aged product includes the diameters with the calculated lowest balloon rupture mean due to having the lowest calculated hoop strength per balloon material," it is not clear how this was determined. In addition, 5.0x12mm size baseline samples had 2 failures, for which the root cause could not be found. Therefore, the 5.0x12mm samples appear to be empirically the worst case and should also be tested post-aging.

c. Please clarify what size stents were used for each balloon size tested.

Sponsor Response/ Reviewer Comments:

a. Sponsor states that there are no 1.5mm diameter stents approved. The proposed indication associated with post-stent dilatation is applicable only to the 2.00 mm through 5.00 mm balloon diameters. There are 2.0mm diameter stents approved such as Abbott's Multi-Link 8 stent. *This response is **acceptable**.*

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b. *For the Mini TREK the 2.0mm diameter size tested is the only Mini TREK size that can be used in stent (post dilation indicated for 2-5mm balloons).* The sponsor references the same burst pressure/balloon rupture aging engineering study they performed in reference to Q11 above. Sponsor states that while each size met all specifications, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters, to justify the selection of these device sizes for aged device testing.

At baseline testing, the 5.00 mm x 12 mm had two samples which did not achieve the required 10 cycles for Balloon Fatigue Within a Stent testing. An additional 29 samples were added to the to the Balloon Fatigue Within a Stent testing, which satisfied the requirement of 10 repeated inflations with 95% confidence and 90% reliability. Sponsor states that since the 5.00 x 12 mm met the fatigue requirement for within a stent, the original worst case size selection is still valid. *I do not entirely agree with this statement given that when the same sample size was tested as other device sizes, the 5x12mm devices had 2 failures while other sizes had none. While additional testing to almost double the total sample size did demonstrate a passing result, this would indicate that the sample size to begin with may have been insufficient. . It appears that the sponsor did perform burst pressure and fatigue (not in stent) testing, for 5.0x12mm sizes in the engineering study, but the data does not clearly demonstrate that even at baseline, that the 2.75mm is worst case.*

(b)(4)



Question 13. In your Balloon Rupture test, you did not include 2.00 x 30mm and 1.50 x 15mm devices although these sizes showed the lowest burst pressure at baseline. Please repeat Balloon Rupture testing including these device sizes and provide a complete test report. Please also provide a statistical comparison between the burst strengths of aged and baseline samples, and if there is a statistically significant decrease, please provide a scientific rationale as to why this decrease does not raise a safety concern.

Sponsor Response/Reviewer Comments: *Note that in the deficiency 1.5x15mm should have been 5.0 x15mm which the sponsor noted.*

The sponsor references the same burst pressure/balloon rupture aging engineering study they performed in reference to Q11 above. Sponsor states that while each size met all specifications, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters, to justify the selection of these device sizes for aged device testing. Abbott also acknowledges that the baseline data gives the appearance that the 2.00 mm x 30 mm and the 5.00 mm x 15 mm represent worst case sizes, but that based on the conclusions presented in the engineering study of aged balloons (above), this anomaly can be attributed to lot-to-lot variation and does not invalidate the original conclusion that the 1.50 mm and the 2.75 mm diameters represent the worst-case sizes for single layer and co-extruded balloons respectively, when tested for balloon outputs. *It appears that the sponsor did perform burst pressure and fatigue (not in stent) testing, for 5.0x12mm sizes in the engineering study, but the data does not clearly demonstrate that even at baseline, that the 2.75mm is worst case. Without testing with a statistically justified sample size from each lot, the sponsor cannot simply conclude that the variations seen between the worst case device sizes for aged and un-aged devices are due to lot-to-lot variability*

The sponsor provided a statistical comparison of aged and unaged devices (for sizes tested in both). For the 1.50 mm x 20 mm, the analysis shows a statistically significant increase. *This does not raise a*

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concern, as it indicates aging did not adversely affect RBP. For the 2.75 mm x 30 mm, the analysis shows a statistically significant decrease (17 vs 20atm RBP). The sponsor attributes this difference in rupture at baseline and aged to lot-to-lot variability. They state that this apparent significant decrease in aged samples does not raise a safety concern because all baseline and aged units meet the finished product specification of 206 psi (14 atm) minimum at 95% confidence / 99.9% reliability. *While this decrease is acceptable for RBP, since the RBP acceptance criteria is 14atm, the sponsor includes information up to 17atm in their labeling (which is within the allowable limit for labeling of 25% above RBP). Based on their engineering study, RBP of the 2.75mm balloon was calculated to be 242psi (16.5atm) post aging, and 255psi (17atm) from their Balloon Rupture test provided in the original submission. From the Balloon Compliance test submitted in the original submission, however, it does not appear that any of the ~17 samples tested failed at 255psi or lower. These data do not clearly demonstrate that with 99/95 confidence and reliability, the balloon would not fail at 17atm, which is the highest value listed in their compliance chart, in post-aged samples. The sponsor should modify their labeling accordingly (if needed).*

Deficiency:

8. Please address the following concerns regarding your Balloon Rupture test:
   a. Per our Guidance *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* the compliance chart may include pressures up to (but not exceeding) 25% above the RBP, if you provide data and statistics demonstrating that 99% of the balloons will not fail at the listed pressure with 95% confidence. It is unclear from the testing provided whether 99% of your catheters will not fail at 17 atm with 95% confidence, post aging, per the compliance chart in your IFU. Please clarify.
   b. If you determine that your data do not support the 17 atm failure pressure, please revise your compliance chart accordingly.

Question 14. Please address the following concerns regarding Balloon Rupture Within a Stent testing:

a. You did not perform this test using 1.50mm x 6mm size (smallest diameter x shortest length) device at baseline or post-aging. Please repeat testing using 1.50 mm x 6 mm size devices and provide a complete test report, or provide a scientific rationale for the omission of testing using this device size.

b. Please clarify what size stents were used for each balloon size tested.

Sponsor Response/ Reviewer Comments:
a. As noted in Q12 above, sponsor states that there are no 1.5mm diameter stents approved. The proposed indication associated with post-stent dilatation is applicable only to the 2.00 mm through 5.00 mm balloon diameters. There are 2.0mm diameter stents approved such as Abbott's Multi-Link 8 stent. *This response is* ***acceptable****.*

(b)(4)

[redacted]

Question 15. Please address the following concerns regarding your Balloon Compliance testing:

a. The rationale behind the device sizes selected for post-aged testing was not clear. Please repeat Balloon Fatigue using aged samples of all "corner sizes" for both the MINI TREK and TREK catheters or provide a scientific justification for the sizes used for post-aged samples.

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b. It appears that there are different numbers of samples tested at different inflation pressures, in some cases with an increase in sample number with increasing pressure. Please clarify why there are a different number of samples at different inflation pressures.

c. Please provide a statistical comparison of balloon diameters at nominal and rated burst pressure between baseline and aged samples to demonstrate that aging has no significant effect on balloon compliance.

Sponsor Response/ Reviewer Comments:
a. Sponsor states that because there is no worst case size for compliance, the balloon compliance testing is collected concurrently with balloon rupture, the 1.50 x 20 mm and 2.75 x 30 mm size selections were based on the sizes used for balloon rupture testing. As addressed in Question 11 and 13, an engineering study identified the 1.50 mm and 2.75 mm sizes as worst case for balloon rupture testing. *It appears that the sponsor perform burst pressure and fatigue (not in stent) testing, for 5.0x12mm sizes in the engineering study, but the data does not clearly demonstrate that even at baseline, that the 2.75mm is worst case.*

b. Sponsor clarifies that during the compliance test, the balloon is submerged under water and inflated to the specified pressures, starting at 2 atm and increasing in 1 atm increments until rupture. A laser micrometer records the diameter measurement. Data are evaluated by comparing each compliance reading with the reading from the previous pressure, and if a balloon decreases in diameter with respect to the previous reading, it is considered to be erroneous and that data point is excluded from the analysis. Erroneous readings can be caused by environmental conditions such as air bubbles in the laser field. Balloon compliance is measured for each sample starting at 2 atm and is measured until the balloon ruptures; therefore, multiple measurements are taken on the same balloon. Data at each pressure are evaluated and erroneous data points are excluded. Although the number of samples tested remains the same, the sample size at each specific pressure may vary depending on the number of erroneous data points that are excluded.

c. The sponsor provided a statistical comparison for the 1.5mm and 2.75mm balloons at baseline and after 2yr aging. For the 1.50 mm balloon diameter, at both nominal pressure and RBP, the aged samples had smaller outer diameters than the baseline samples, by 0.02 and 0.03mm respectively. However, all baseline and aged units meet the finished product specification for outer diameter at nominal pressure. For the 2.75 mm balloon diameter, at both nominal pressure and RBP, the aged samples had larger outer diameters than the baseline samples, by0.03 and 0.05mm respectively. Again, all baseline and aged units meet the finished product specification for outer diameter at nominal pressure. *The differences between aged and baseline appears to be on the same order as the standard deviation, and although the differences are statistically significant, they are small and unlikely to have any clinical impact. This response is* ***acceptable****. Note that the sponsor attributes variation between aged and unaged to be due to lot-to-lot variation, but have not provided data to support this assertion.*

Question 16. *In your Distal Catheter Tensile (midlap seal) test, you did not perform a statistical analysis between aged and unaged samples. It appears that the TREK samples (5.0x15mm and 2.25x30mm) showed a substantial decrease in this property with aging, with a minimum strength of 1.5lbs in one of the samples. Please provide a statistical comparison of the aged and unaged samples and provide a scientific rationale for why you believe the decrease in Distal Catheter Tensile Strength with aging does not raise a safety concern.*

Sponsor Response/ Reviewer Comments: The sponsor performed a statistical comparison between aged and un-aged samples as requested. No statistically significant difference in Distal Catheter Tensile (midlap seal) was observed for the MINI TREK sizes. For the TREK sizes, a statistically significant difference in tensile values between aged and un-aged samples was observed, however, all data points exceed the 1.1 lb minimum product specification requirement. *From the original submission, the lowest tensile value for the TREK was 1.5lbs, with a mean of 2.1±0.34lbs. Even the lowest value is above the acceptance criteria of 1.1lb, so this decrease is* ***acceptable****. If this trend of decreasing tensile strength*

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with aging continues, extension of shelf life would not be acceptable. Warning rolled into tensile strength deficiency above.

Question 17. Please repeat Catheter Coating Particulates Testing and address the following concerns in your repeated testing:

a. It appears you have flushed your tortuous tracking fixture after the guidewire and guide catheter were placed in the fixture, and discarded the effluent. Since patients would be exposed to the particles generated from these accessory devices necessary for the use of your device, please collect this effluent and report the total particulate count for this effluent.

(b)(4)



It is not clear how the guide wire and guide catheter were flushed; specifically whether the inside and outside of the guide catheter was flushed. However, the outside is rinsed per IFU before testing, so the contribution from the outside of the catheter is expected to be minimal. The amount of particulates generated in total appear to be very low, and does not raise a concern. This response is ***acceptable****.*

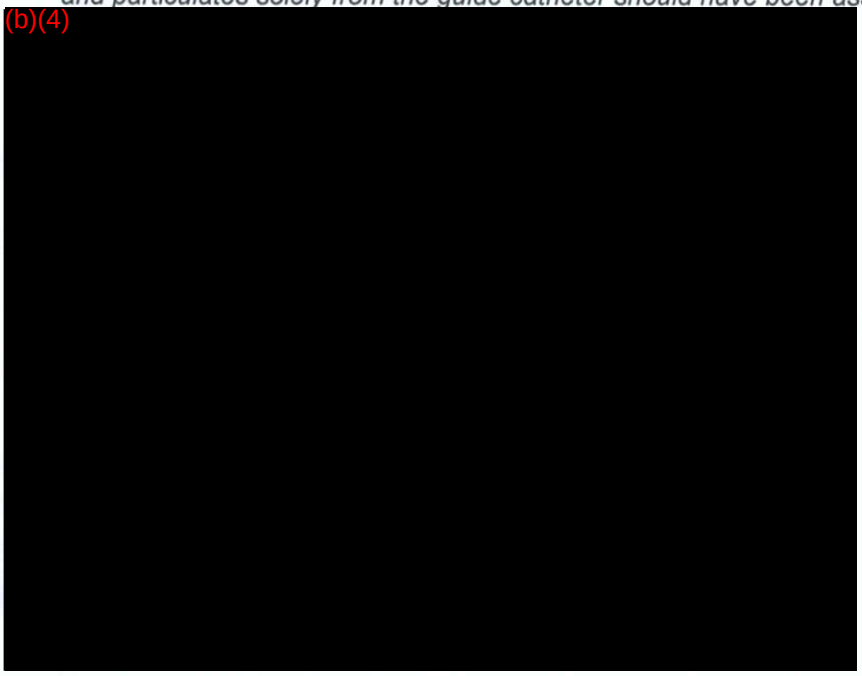
b. It was unclear from the photograph of your tracking fixture, whether the whole catheter is tracked through the fixture, or if only a distal segment is inserted into the fixture. Please make sure that the fixture is sufficiently long such that the whole patient contacting parts of the catheter can be tracked into the fixture, and particulates generated from this entire length are captured. In addition, you did not provide the critical dimensions of your test fixture (radius of curvature, diameter of track, etc.). Nevertheless, your fixture appears to be less tortuous than the coronary artery model in ASTM F 2394 – 04 Fig x2.4, and lacks the aortic arch portion. Please revise your tracking fixture to match the dimensions in ASTM F 2394 – 04 Fig x2.4 or equivalent.

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Sponsor Response/ Reviewer Comments: The whole patient contacting portion of the device enters the test system. The device is inserted from the rotating hemostasis valve (RHV). *It appears that with this test fixture, only the inside of the guide catheter would be assessed for particulates since there is no simulated vessel (i.e. the guide catheter is connected to the RHV on the proximal end and the tortuosity block on the other end. Specifically, the particulates from tracking the guide catheter would not be assessed in the current test setup. Nevertheless, this test setup would assess particulates generated from the guide catheter (and guidewire) interactions with the subject TREK and MINI TREK catheters, and particulates solely from the guide catheter should have been assessed in the review of those*

(b)(4)



The sponsor has added an aortic arch to their tortuosity block to more closely match the ASTM F 2394 – 04 Fig x2.4 fixture:

(b)(4)



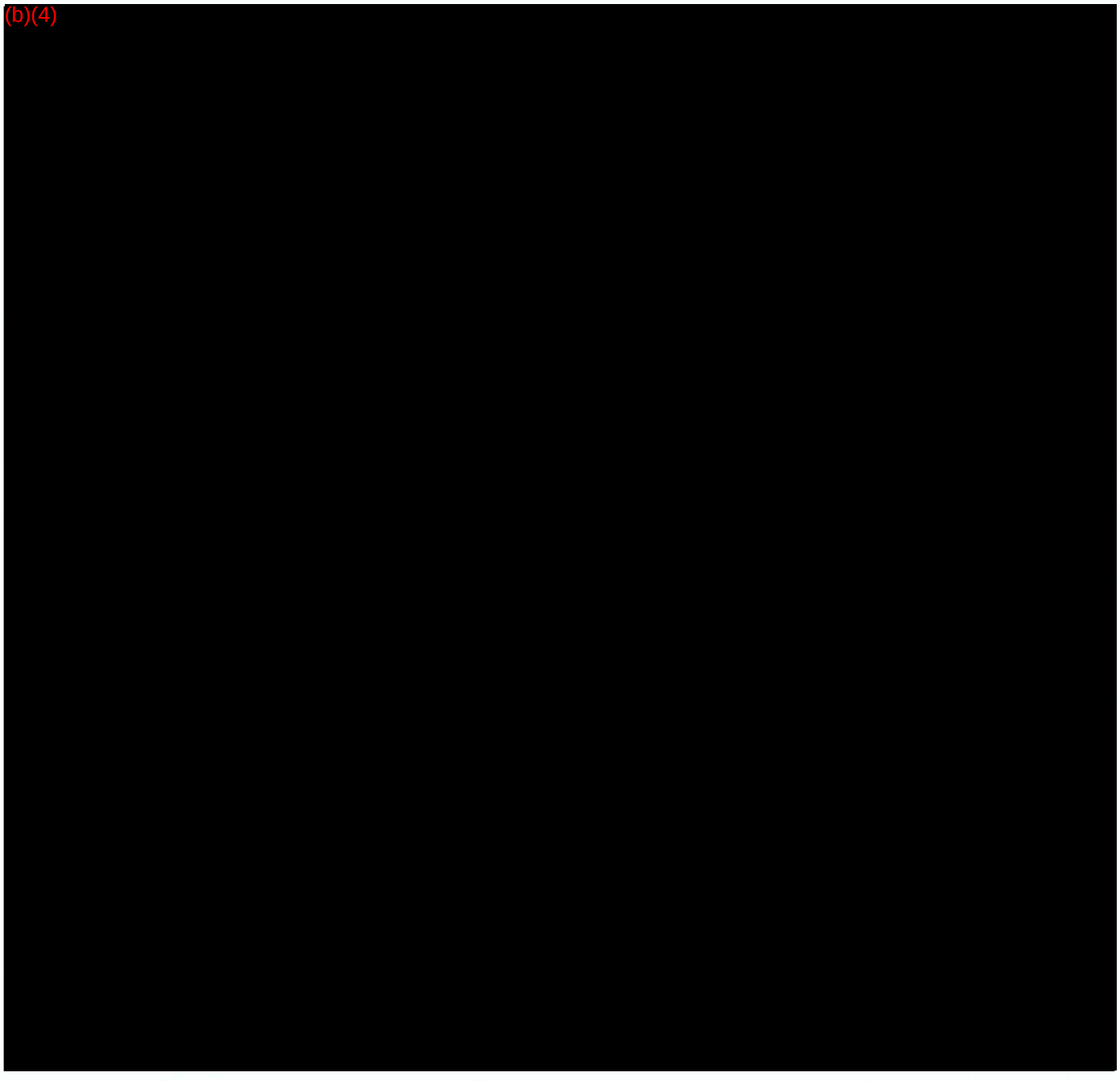
ASTM figure x2.4 (R~0.5"). However, it appears the guide catheter overall is somewhat bent between the RHV and the tortuosity block, and the difference in curvature for the aortic arch segment is unlikely to significantly impact particulates generation due to the overall wide curvature of the aortic arch. It appears the guide catheter is bent into the aortic arch curve.

The sponsor compared the data from testing using the revised fixture with the aortic arch loop and the original fixture which did not have this portion. There were significantly fewer particulates (50µm bin) in the testing with the aortic arch

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(b)(4)

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(b)(4)

[redacted]

e. Please perform a validation test for your test fixture (spike and recovery test using particles of know size and quantity, for each size bin outlined in part d above), and provide a complete test report for this validation. FDA is amenable to reviewing your test protocol informally prior to test initiation.

Sponsor Response/ Reviewer Comments: The sponsor performed spike and recovery testing using their revised test fixture including the aortic arch (Appendix 17-1).

Acceptance criteria:

- 90 ≤ percent recovery; ≤ 110 for 10 and 25 micron spheres
- 75 ≤ percent recovery; ≤ 110 for 50 and 70 micron spheres

Duke Scientific standard spheres were injected into the proximal end of the guide catheter. Each of the 3 test fixtures were assessed and a 15mL aliquot of effluent was measured using 2 different light obscuration particle counters. It appears n=4 samples were used for 10 and 25µm bins, and n=2 for the 50 and 75µm particle bins. Effluent samples were also re-tested after a 'cleanliness check' of the particle counter and 'additional degas procedure'. All of the initial effluent test samples passed, while one measure each of the 25, 50 and 75µm bin samples failed in the retest. This indicates that the extra steps taken (cleanliness check and degas) may have introduced additional particles or counting error. *Overall, the validation results were acceptable and met the acceptance criteria.*

Note: The TLT2065633-40 fixture (used for embolic fatigue per spike and recovery test protocol) and TLT2065633-25 (used for the 2.0mm balloon) uses the same tortuosity block but a different size tubing in the block (per 11/24/10 email). It appears the tubing used for the spike and recovery test was larger than

(b)(4)

[redacted]

f. Please clarify what accessory devices (guide catheter and guidewire) and stents were used in your test.

Sponsor Response/ Reviewer Comments:

The following accessory devices were used during Catheter Coating Particulate Testing:

- Hi-Torque Extra S'port Guidewire, K021285, Cleared 5/2/2002
- VIKING Guiding Catheter, K972484, Cleared 9/26/1997
- MULTI-LINK MINI VISION Coronary Stent, P020047/S003, Approved 9/10/2004
- MULTI-LINK VISION Coronary Stent, P020047, Approved 7/16/2003

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- MULTI-LINK ULTRA Coronary Stent, P970020/S021, Approved 9/8/2000

(b)(4) [redacted]

clean with gauze soaked with sterile, heparinized normal saline and stored. Prior to reinsertion, the balloon should be submerged in sterile, heparinized normal saline to reactivate the coating." However, this process of wiping with gauze and reinserting was not performed for your particulates test. Please include these steps in your new particulates testing.

Sponsor Response/ Reviewer Comments: The sponsor states that wiping with gauze to remove dried blood particles is standard cath lab practice, but how this is performed is outside the control of the sponsor. They state that particulates testing is to assess and reduce particulates from manufacturing. *Given that we do not request other manufacturers to assess particulates post wiping with gauze, or other manipulations of the device that may occur in the cath lab, this response is* ***acceptable****.*

h. You have performed 3 inflations in the overlapped stents in your fixture. The maximum number of inflations was not specified in your instructions for use (IFU). Please perform the same number of maximum inflations in your particulates test, to the maximum labeled diameter, as you intend to state in your IFU, and update your IFU accordingly.

Sponsor Response/ Reviewer Comments: Abbott Vascular has revised the IFU to include the maximum number of inflations (10 within a stent, 20 without a stent; Attachment 19). For particulates testing, the 3 inflations were performed to 17atm, which is the max labeled, and above the RBP of 14atm, to simulate a worst case for particulates testing. *Since the balloon fatigue testing within and without a stent to RBP passed, 10 and 20 inflations respectively, this labeling is appropriate. See 8/19/10 email to sponsor. This response is* ***acceptable****.*

i. Please perform a visual assessment of your catheter coating integrity after particulates testing. We recommend that you appropriately quantify characteristics such as continuity and voids in the coating, using a sufficient magnification to visualize the defects. Please also include representative images (including worst-case) in your test report.

Sponsor Response/ Reviewer Comments: *The sponsor used a red dye to visualize the coating on the* 4.00 x 30 mm size devices, deemed to be the worst case. The dyed catheters were tracked through the fixture used for particulates assessment. The following locations on the coated region were examined under 30x magnification:

(b)(4) [redacted]

Deficiency:

9. Please address the following concerns regarding your Particulates Testing:

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c. You state that for baseline testing, the 2.0 x 6mm and the 5.0 x 15mm devices were tested as representative of the smallest and largest sizes (diameter and length) in the balloon matrix that are indicated for the post-stent dilatation indication, and the 4.0 x 30mm devices were tested as a worst case because it has the largest balloon surface area that contacts the stents. You also justify testing only the 4.0 x 30mm devices post aging because this size had the highest particulation at baseline. Since you did not test the 2.0 x 30mm size, which is one of the 4 corners of your device size matrix, at baseline, we cannot determine conclusively that the 4.0 x 30mm is the worst case size. In particular, the 2.0 x 6mm devices had greater than $1/5^{th}$ the mean particulates count of the 4.0 x 30mm devices. This suggests that the 4.0 x 30mm devices may have appeared to be worst case due to the longer length of the balloon, but in fact, the 2.0 x 30mm devices may be the true worst case devices in terms of particulates generation. Please repeat testing using the 2.0 x 30mm devices at baseline and provide an updated test report.
d. If you determine from the 2.0 x 30mm devices tested at baseline that this size is the true worst case in terms of particulates generation, please also perform particulates testing using 2.0 x 30mm devices aged to your proposed shelf life. Please make sure to incorporate recommendations made in deficiency #17, such as including a ≥50µm particle bin size, accounting for particles from flushing the accessory devices after placement, etc. In addition, if the 2.0 x 30mm devices are determined to be the worst case, please also perform a visual assessment of the coating.
e. Please make sure to include both RX and OTW devices for this additional testing, or provide a scientific justification for only using one device configuration.
f. In your particulates validation testing, it appears you have used a slightly different 2.0mm device size test fixture than what was actually used to assess particulates generation (per November 24, 2010 email). Specifically, the tubing diameter used within the tortuosity base plate was slightly different. While this is acceptable since validation results for the 4.0mm device fixture with similar tortuosity to the 2.0mm fixture and a further larger tubing size showed similar results, please acknowledge that for future testing you will use the same exact test setup and methods in your validation testing as in your actual device testing. Please also acknowledge that if you have differences in your validation test setup or protocol (flushing etc.) that you will clearly identify and justify these differences in future submissions.

Question 18. It appears that you have used a room temperature value of 20°C (68°F) to calculate your accelerated aging factor, which is less conservative than using a more typical value for room temperature (23-25°C). FDA believes that the devices will be exposed to ambient temperatures above 20°C during transport and storage. If a room temperature value of 25°C was used, 65 days of aging at 55°C (functional testing) and 46 days of aging at 60°C (packaging) would be equivalent to 520 days, rather than 2 years as you have calculated. Please either reduce your shelf life claim in the future marketing application to match the shelf life duration supported with testing using a more conservative value for room temperature, perform additional shelf life testing to support your proposed 6 month shelf life, or provide a scientific justification for why you believe a room temperature value of 20°C is appropriate.

Sponsor Response/ Reviewer Comments: The sponsor recalculated their accelerated aging based on the Arrhenius equation in ASTM F1980 (Af= aging factor).

(b)(4) [redacted]

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(b)(4)



The sponsor has revised their shelf life to 1 yr for the RX and 6 months for OTW based on these calculations. This response is ***acceptable****.*

Question 19. Please address the following concerns regarding your Instructions for Use (IFU):

a. Please include the maximum number of inflation cycles, both in a stent (post dilatation) and not in a stent

b. The Rx only symbol was not included in the graphical symbols glossary at the end of your IFU. Please add the symbol to your glossary. Please also add the statement "Caution: Federal law restricts this device to sale by or on the order of a physician."

c. Please provide a red-lined copy of your IFU with the above changes incorporated.

Sponsor Response/ Reviewer Comments:

a. The sponsor has added the max number of inflation cycles as requested. *This response is* ***acceptable****.*

b. Abbott Vascular has chosen to use the "Rx only" symbol as an alternative to the prescription *labeling* requirements, based on the Guidance for Industry – Alternative to Certain Prescription Device Labeling Requirements, January 21, 2000 which states:

> "CDRH would like to minimize the burden on manufacturers, repackers, relabelers and distributors that face a variety of labeling requirements and changes. Therefore, CDRH, in its enforcement discretion, does not intend to object to the use of the statement "Rx only" as an alternative to the prescription device labeling statement "Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)."

Additionally, this guidance states that, "additional prescription statements are not required if the 'Rx only' symbol is present." *This response is* ***acceptable****.*

c. The sponsor provided a red-lined copy of the revised IFU in Appendix A19-1. *This response is* ***acceptable****.*

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Supplement S001—Response to December 2, 2010 Additional Information Letter

After the review of the original PMA submission, there were outstanding deficiencies. The Sponsor responded to these deficiencies in Amendment A002 and the document was converted to a 510(k). PTCA catheters were reclassified from Class III to Class II on October 8, 2010. After review of the Sponsor's response Dr. Erica Takai had outstanding deficiencies that were sent to the Sponsor in an Additional Information Letter on December 2, 2010. Below are the deficiencies, the Sponsor's response and reviewer comments. The Sponsor originally responded to our letter on December 7, 2010, but this information was logged in as an 'add to file' because we had not received all of the information from the MAF holders. Ashley Boam (Chief, ICDB) had been in contact with the Sponsor stating that the file was back on hold. As of December 17, 2010 we had received all the information from the MAF holders (see Jennifer Goode's e-mail enclosed and discussion below). On December 23, 2010 Ms. Boam and I received an email from Ms. Marjorie Shulman, 510(k) Staff, stating that we needed a letter from the company to put the file back on the clock. On December 29, 2010 I contacted the Sponsor and stated that they needed to submit such a letter. A letter was received by the Sponsor on December 30, 2010 which put the submission back on the clock. All email correspondence is enclosed.

1. Please address the following concerns regarding biocompatibility testing performed on your TREK/MINI TREK OTW devices:
    a. For Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Hemolysis (indirect method), and Material Mediated Pyrogenicity tests, please clarify the time between extract preparation and use, and storage conditions if stored.

Sponsor's Response:
The time between extract preparation and use, and storage conditions if stored for each of the above listed tests is as follows:

- Sensitization – Testing extracts were stored and tested within the time periods stated below:
    - Induction 1 - within 10 hours of the time removed from extraction; held at room temperature
    - Induction 2 - within 6 hours of the time removed from extraction; held at room temperature
    - Challenge - within 6 hours of the time removed from extraction; held at room temperature
- Intracutaneous Reactivity – Testing extract was tested within 4 hours of the time removed from extraction; held at room temperature during storage.
- Acute Systemic Toxicity – Testing extract was tested within 2 hours of the time removed from extraction; held at room temperature during storage.
- Hemolysis (indirect method) – Hemolysis testing extracts, including the indirect method, were tested approximately 1 hour after removal from extract; held at room temperature during storage.
- Material Mediated Pyrogenicity – Testing extract was tested within 2 hours of the time removed from extraction; held at room temperature during storage.

Reviewer Comments: I e-mailed Ms. Goode, DCD biocompatibility expert, on January 6, 2010 and requested that she review the Sponsor's response. Ms. Goode responded to my e-mail on January 7, 2010. Ms. Goode stated that the ISO 10993-12 standard (for extraction) says that, in general, extracts should be used within 24 hours. Therefore, the

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*Sponsor's response is **acceptable** since all extracts were used under 24 hours and were held at room temperature. E-mail enclosed.*

b. Please acknowledge that for all future submissions, your test reports will include the following information:
   - whether or not extracts were manipulated (filtered, centrifuged, etc.);
   - condition of extract; and
   - Time between extract preparation and use, and storage conditions if stored.

Sponsor's Response:
Abbott Vascular acknowledges and will comply with the request for the above requested extract information to be included for all future test reports in which extracts were to be prepared for testing.

*Reviewer Comments: The Sponsor's Response is **acceptable.***

2. In your Soft Tip to Inner Member Tensile test for the OTW TREK catheters, it appears that the 2.25 x 30mm size experienced a significant decrease in tensile strength between baseline and 6 months. Please provide a statistical comparison of aged and baseline results, and provide a scientific or clinical justification for why you believe a significant decrease in tensile strength with aging does not raise a safety concern. Please acknowledge that for future submissions, you will provide statistical comparisons for performance tests with quantitative metrics to demonstrate whether a significant negative effect on performance was observed post-aging. In addition, please acknowledge that you will not extend your shelf life if any of your devices do not meet the acceptance criteria set at baseline, for all of the tests performed.

Sponsor's Response:
All samples met the product specification and ISO 10555-1:1997, *Sterile, single-use intravascular catheters - Part 1: General requirements*, requirement of 1.12 lbf for baseline and aging time points with no apparent trend.

Abbott Vascular recognizes that the Soft Tip to Inner Member Tensile results for the TREK OTW 2.25 mm x 30 mm size experienced a significant decrease in tensile strength between baseline and 6 months although they still met the specification. As shown in Figure A2-1, additional post-aged results have been generated for 1 and 2 year accelerated aging (55°C elevated temperature, 20% humidity, 25°C ambient temperature). The one (1) and two (2) year aging results demonstrate that there is no negative aging trend.

Abbott Vascular acknowledges the request to provide statistical comparisons for performance tests in future submissions, as appropriate, to assure that the device meets its specified requirements throughout its shelf life.

Abbott Vascular acknowledges the request that shelf life will not be extended if the test results do not meet the acceptance criteria. As specified in the accelerated aging testing protocol, shelf life will only be extended upon successful completion of the accelerated aging testing at the associated time point.

Reviewer Comments:
It is noted that all samples, both baseline and 6months aged product met the pre-determined acceptance criteria. The Sponsor provided additional 1 and 2 years accelerated aging test results which demonstrated no negative trend. Although the tensile strength decreased from baseline compared to 6 months, there was no negative trend in the 1 and 2 year accelerated testing. There are no safety concerns since the results met the

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acceptance criteria. The Sponsor has acknowledged our requests. This response is ***acceptable****.*

3. For the colorant being used in the white foil proximal marker, please acknowledge your understanding that additional information is being requested of CFC International regarding their Type III DMF #17442 letter of authorization dated August 27, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

   Sponsor's Response:
   Abbott Vascular acknowledges that additional information is being requested of CFC International regarding their Type III DMF #17442 with responses to be provided interactively via email and subsequently, once found to be sufficient, through official submission to the master file. It is Abbott Vascular's understanding that once the emailed information received from the Master File Holder is found to be sufficient that clearance of this 510(k) will not be dependent upon the file holder's official submission to their master file.

   Reviewer Comments:
   On December 17, 2010 Ms. Jennifer Good, DCD Biocompatibility expert, e-mailed me regarding the White Foil (titanium dioxide) from CFC international stating that we have not received any information on the size range of the particles used in the colorant. On December 20, 2010 Ms. Goode received a brochure from the manufacturer of the pigment that stated that the particle size range is between 270 and 300 nanometers. On the same day, Ms. Goode stated that the particle size for the Titanium Dioxide used in the White foil is in the range of 200-300nm, because this is an interventional catheter, no additional questions need to be asked. See Ms. Goode's literature review (HSDB risk information) on nano TiO2, enclosed. Ms. Goode sent an email to the contact at CFC International stating that we have no additional question regarding this colorant. All e-mail correspondences are enclosed. The Sponsor's response is ***acceptable.***

4. For the aqua colorant being used in the RX Catheter Clip, please acknowledge your understanding that additional information is being requested of Clariant regarding their Type III DMF #10640 letter of authorization dated September 10, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

   Sponsor's Response:
   Abbott Vascular acknowledges that additional information is being requested of Clariant regarding their Type III DMF #10640 with responses to be provided interactively via email and subsequently, once found to be sufficient, through official submission to the master file. It is Abbott Vascular's understanding that once the emailed information received from the Master File Holder is found to be sufficient that clearance of this 510(k) will not be dependent upon the file holder's official submission to their master file.

   Reviewer Comments:
   On December 17, 2010 Ms. Jennifer Good, DCD Biocompatibility expert, e-mailed me regarding the Aqua colorant (titanium dioxide) from Clarinet (supplier Dupont) stating that the TiO2 has a size range of 200-300nm which is an acceptable range. See Ms. Goode's literature review (HSDB risk information) on nano TiO2, enclosed. E-mail correspondence between Ms. Goode and Clarinet including the letter confirming the particle size of the TiO2 is enclosed. The Sponsor's response is ***acceptable.***

5. For the colorant being used in the purple colorant used in the side arm, please acknowledge your understanding that additional information is being requested of CFC International regarding their MAF#0353 letter of authorization dated August 26, 2010. The Master File Holder is being asked

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to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

Sponsor's Response:
Please note that the Master File Holder of MAF #0353 is Bayer Material Science and not CFC International as indicated by the Letter of Authorization, dated August 26, 2010, and included in Appendix A7-4 of P810046/S002.

Abbott Vascular acknowledges that additional information is being requested of Bayer Material Science regarding their MAF #0353 with responses to be provided interactively via email and subsequently, once found to be sufficient, through official submission to the master file. It is Abbott Vascular's understanding that once the emailed information received from the Master File Holder is found to be sufficient that clearance of this 510(k) will not be dependent upon the file holder's official submission to their master file.

Reviewer Comments:
On December 17, 2010 Ms. Jennifer Good, DCD Biocompatibility expert, e-mailed me regarding the Purple colorant from Bayer stating that the extraction studies showed no elution of the colors out of the polymer and that the data provided sufficient reassurance that he colors won't leach during use of this device. Bayer also confirmed that the colors comply with 21 CFR 170.39. E-mail correspondence between Ms. Goode and Bayer are enclosed. The Sponsor's response is ***acceptable.***

6. In your response to deficiency #10 of our August 9, 2010 letter (P810046/S235) regarding Crossing Profile, you indicate that your label claims compatibility with 5F guide catheters based on a 0.056" ID minimum for these guide catheters. However, your IFU currently only states "Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery" and are not limiting compatible accessories to 5F guide catheters. The labeling language regarding guide catheter selection is acceptable since you have identified the French size of the thickest part of each device size in your labeling (3.4Fr for all devices). However, it is unclear whether your testing sufficiently assesses the compatibility of the guide catheters expected to be used. Specifically, in response to deficiency #17f regarding Particulates testing (combined with simulated use testing), you have identified the accessory devices used in your testing but did not specify the accessory device sizes. Please provide this information.

Sponsor's Response:
Abbott Vascular assessed guiding catheter compatibility through simulated use by evaluating device delivery, contrast injection, and pullback after inflation performance with the guiding catheter. Additionally *in vitro* bench testing evaluated Crossing Profile and Refolded Balloon Profile for guiding catheter compatibility, which was included in Section 6.4 of P810046/S235 (RX) and in Attachment 20, Section 6.4 of P810046/S235/A002 (OTW).

The sizes of the accessory devices used for Particulate Testing and provided in P810046/S235/A002 in response to deficiency #17f are provided in Table A6-1.

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Reviewer Comments:
The Sponsor has provided the accessory device names and sizes used in their particulate testing in Table A6-1. The Sponsor also provided a diagram in Figure A6-1 that shows the guiding catheter interaction. The Sponsor has provided the requested additional information. This response is ***acceptable.***

7. Please address the following concerns regarding the lack of testing using the 5.0x15mm device size for Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing post-aging:

   a. You have performed an engineering study using baseline samples to identify the worst case device size for the TREK and Mini TREK catheters (RPT2073031), which examined Balloon Fatigue (without a stent) and Balloon Rupture. It is unclear from this test report whether the 2.75mm balloon is indeed the worst case when compared to the 5.0mm balloons, in part because the data from the shortest (6mm) and longest (30mm) were pooled. You have also provided Balloon Rupture testing using devices determined to be worst case from your initial engineering study (p. 6-72 of P810046/S235). From the test data provided in your P810046/S235 submission, the 5.0 x 15mm and 5.0 x 12mm size devices had the lowest Rupture Pressure and RBP at baseline, lower than that of the 2.75 x 30mm devices. Therefore, from the data presented, it is unclear whether the 2.75 x 30mm diameter devices used for post-aged testing is the worst case compared to one

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of the 5.0mm diameter devices. Please perform Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing on your worst case 5.0mm device size aged to your proposed shelf life, or provide additional data to support the 2.75 x 30mm size as the worst case.

Sponsor's Response:
Abbott Vascular continues to support the 2.75 mm x 30 mm, where data was collected from multiple lots, worst case size selection based on data presented in the original engineering study (RPT2073031) and baseline data provided in the submission (P810046/S235). Additional data have been included from the 2.75 mm x 30 mm post aged lots that further support the worst case size selection is the 2.75 mm x 30 mm. Table A7-1 provides a summary of the initial engineering study, filing, and post aged results comparing the 2.75 mm (5 lots) to 5.00 mm device sizes (4 lots). Since multiple lots for both sizes were used in the testing, the results confirm that the 2.75 mm balloon is the worse case size.

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[redacted]

Reviewer Comments:
It is difficult to determine if the 2.75mm balloon is the worst case size based on the information contained in Table A7-1. Based on the data summary by diameter for rated burst pressure (RBP), 244psi vs 263psi for 2.75 vs. 5.00mm respectively, it seems like the 2.75mm size would be worst case. However, these RBPs (average) included the accelerated aged samples for the 2.75mm sizes. Without using any aged product in the calculations, the average rated burst pressure for the 2.75mm balloon size would be 261psi (125 samples) and for the 5.0mm balloon would be 253psi (85 samples) which would be a lower RBP. Therefore, the worst case without the accelerated samples is the 5.00mm balloon. After reviewing table A7-1 it seems like the differences between the two RBPs (which would lead one to think one is worst case over the other) is very small. Although the Sponsor can not definitely say that the 2.75mm balloon is worst case based on the data they have provided, I believe at this time Sponsor does not need to perform additional testing that was requested in question 7a. The Sponsor's response is ***acceptable.***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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b. You also noted in response to deficiency #13 regarding Balloon Rupture testing, that the data from the baseline 5.0 x 15mm devices give the appearance that this is the worst case size, but attribute this to lot-to-lot manufacturing variations. Since it appears that you have not performed Balloon Rupture testing on different lots for a given device size, we cannot conclude that differences observed between different sizes are due to different lots and not due to the device size. Please keep this in mind, should you choose to provide additional justification for testing the 2.75x30mm devices post-aging.

Sponsor's Response:
Based upon the response provided for Question 7a in support of the 2.75 mm x 30 mm, where data was collected from multiple lots, as a worst case size, no further post-aging testing is being conducted beyond the requirements of the aging protocols (using a 25°C ambient temperature assumption) submitted in P810046/S235/A002.

Reviewer Comments: As noted above, multiple lots for both sizes were used in the testing. The Sponsor did not conduct additional aging testing on the 5.0mm balloon size. The Sponsor's response is ***acceptable****, see above.*

8. Please address the following concerns regarding your Balloon Rupture test:

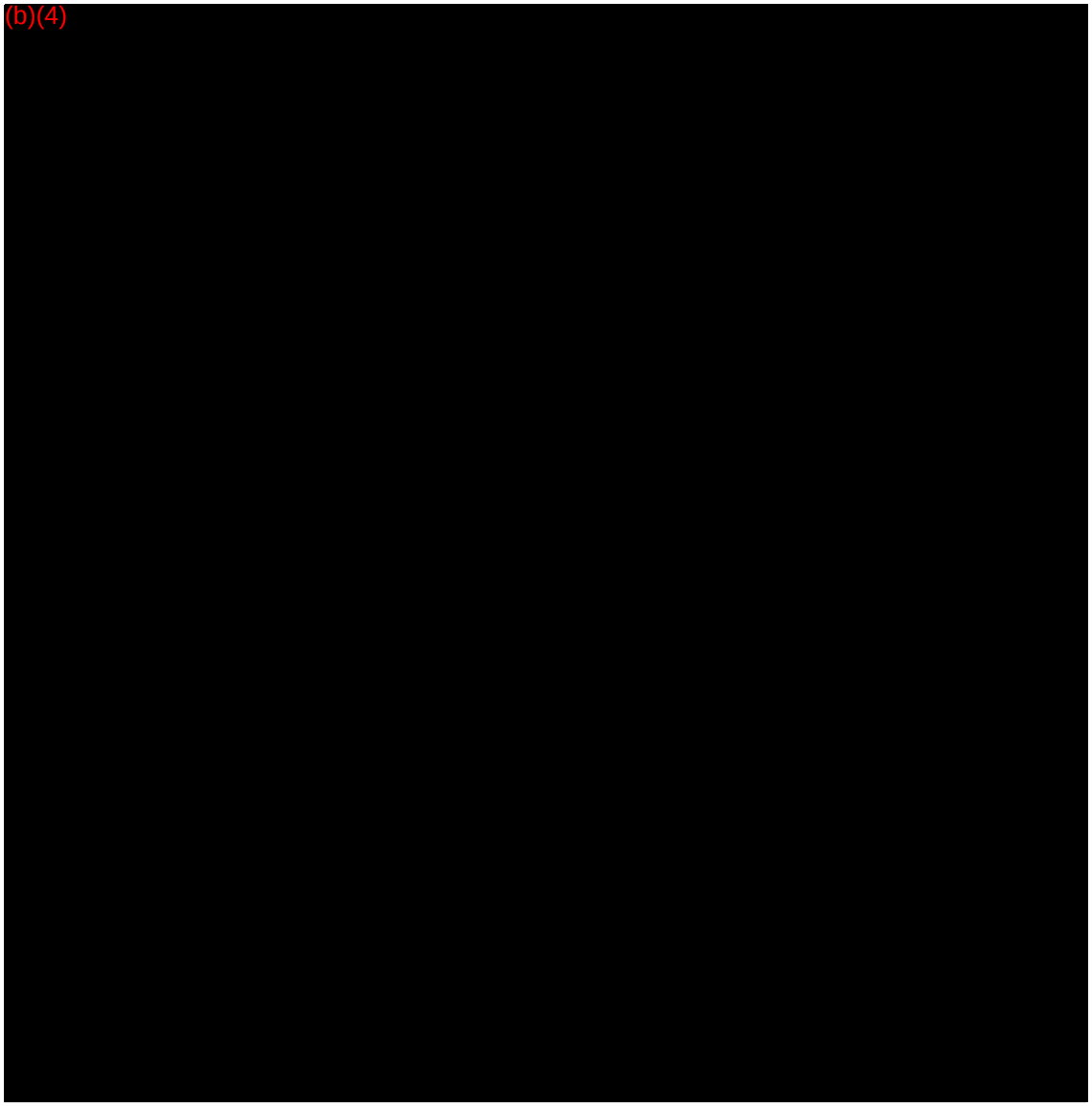
a. Per our Guidance *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* the compliance chart may include pressures up to (but not exceeding) 25% above the RBP, if you provide data and statistics demonstrating that 99% of the balloons will not fail at the listed pressure with 95% confidence. It is unclear from the testing provided whether 99% of your catheters will not fail at 17 atm with 95% confidence, post aging, per the compliance chart in your IFU. Please clarify.

Sponsor's Response:
(b)(4)
[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)



The data presented in Table A8-1 and A8-2 demonstrates that the current labeling is supported to 17 atm with 95% confidence and 99% reliability.

Reviewer Comments: The Sponsor has provided data to support that the current labeling is supported to 17atm with 95% confidence and 99% reliability post aging. The Sponsor's response is ***acceptable.***

b. If you determine that your data do not support the 17 atm failure pressure, please revise your compliance chart accordingly.

Sponsor's Response:
Based upon the information provided in the response to Question 8a, which supports a 17 atm failure pressure, the compliance chart does not need to be revised. The data presented in Table A8-1 and A8-2 demonstrates that the current labeling is supported to 17 atm with 95% confidence and 99% reliability.

Reviewer Comments: The labeling does not need to be revised. The Sponsor's response is ***acceptable.***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118:

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9. Please address the following concerns regarding your Particulates Testing:

   a. You state that for baseline testing, the 2.0 x 6mm and the 5.0 x 15mm devices were tested as representative of the smallest and largest sizes (diameter and length) in the balloon matrix that are indicated for the post-stent dilatation indication, and the 4.0 x 30mm devices were tested as a worst case because it has the largest balloon surface area that contacts the stents. You also justify testing only the 4.0 x 30mm devices post aging because this size had the highest particulation at baseline. Since you did not test the 2.0 x 30mm size, which is one of the 4 corners of your device size matrix, at baseline, we cannot *determine* conclusively that the 4.0 x 30mm is the worst case size. In particular, the 2.0 x 6mm devices had greater than 1/5th *the mean* particulates count of the 4.0 x 30mm devices. This suggests that the 4.0 x 30mm devices may have appeared to be worst case due to the longer length of the balloon, but in fact, the 2.0 x 30mm devices may be the true worst case devices in terms of particulates generation. Please repeat testing using the 2.0 x 30mm devices at baseline and provide an updated test report.

   Sponsor's Response:
   As stated, the 4.00 x 30 mm devices were tested as a worst case as this size has the largest balloon surface area that contacts the stent. This area is calculated as shown below:

   Balloon Surface Area = (Diameter) * (π) * (Balloon Working Length)

   Table A9-1 lists the TREK RX and MINI TREK RX in order of increasing balloon surface area in contact with the stent for this test. The total particulate count per diameter increases with increasing balloon area, however, these results are not one to one. That is, particulate count does not double if balloon surface area is doubled. Particulates are generated from both the coated surface of the catheter shaft and the coated balloon surface. Since the balloon surface area is a small portion of this total coated area it is not expected that the particulate count for a 2.00 mm x 30 mm catheter would be significantly higher than that for a 2.00 mm x 6 mm catheter. Therefore, Abbott Vascular concludes that in this test, the 4.00 x 30 mm

(b)(4) [redacted]

   the balloon surface area calculated above. The Sponsor also provided the particulate count by balloon surface are contacting stent table, Table A9-1 above, that provides the particulate counts of the Trek RX and Mini Trek RX in order of increasing balloon surface are in contact with the stent. It is noted that the 2.00 x 30mm balloon size has no results. From the table, it can be concluded that the devices with the largest balloon are in contact with the stent is correlated with the highest particulate count for all particle sizes except for the 70 micron bin size which only had one particle for both the 4.00x30mm and 5.00x15mm balloon sizes. Based on the low level of particulate generations and the results provided in Table A9-1 it is acceptable that the Sponsor did not provide testing on the 2.00 x 30mm balloon sizes. The Sponsor's response is ***acceptable*** *and there are no concerns.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

b. If you determine from the 2.0 x 30mm devices tested at baseline that this size is the true worst case in terms of particulates generation, please also perform particulates testing using 2.0 x 30mm devices aged to your proposed shelf life. Please make sure to incorporate recommendations made in deficiency #17, such as including a ≥50µm particle bin size, accounting for particles from flushing the accessory devices after placement, etc. In addition, if the 2.0 x 30mm devices are determined to be the worst case, please also perform a visual assessment of the coating.

Sponsor's Response:
The rationale and data provided in response to Question 9a demonstrate that the 4.00 mm x 30 mm catheter is the worst case size for particulate testing. Therefore no additional testing was performed.

Reviewer Comments: *The Sponsor's response is* ***acceptable.***

c. Please make sure to include both RX and OTW devices for this additional testing, or provide a scientific justification for only using one device configuration.

Sponsor's Response:
Based upon the rationale and data provided in response to Question 9a, no additional particulate testing was conducted.

Reviewer Comments: *The Sponsor's response is* ***acceptable.***

d. In your particulates validation testing, it appears you have used a slightly different 2.0mm device size test fixture than what was actually used to assess particulates generation (per your November 24, 2010 email). Specifically, the tubing diameter used within the tortuosity base plate was slightly different. While this is acceptable since validation results for the 4.0mm device fixture with similar tortuosity to the 2.0mm fixture and a further larger tubing size showed similar results, please acknowledge that for future testing you will use the same exact test setup and methods in your validation testing as in your actual device testing. Please also acknowledge that if you have differences in your validation test setup or protocol (flushing etc.) that you will clearly identify and justify these differences in future submissions.

Sponsor's Response:
Abbott Vascular acknowledges FDA's requests to provide the following in future submissions:

The same exact test setup and methods used in validation testing will be used in actual device testing;

Differences in validation test set up or protocol will be clearly identified and justified.

Reviewer Comments: *The Sponsor's response is* ***acceptable.***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)



HART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:
This is a device change to an earlier version of the sponsor's own PTCA catheter.

4. Explain how new characteristics could or could not affect safety or effectiveness:
The new characteristics are similar to other PTCA catheters (materials, sizes, design) and the concerns identified are not new.

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

There are no outstanding questions to send to the Sponsor.

XVI. Contact History

- 12/29/10 email—sponsor stated that they will prepare a letter to take the file off 'hold'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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- 12/13/10 email—sponsor provided Standards forms (FDA 3654)
- 11/24/10 email—sponsor provided requested additional information on testing to determine sizes to be tested post aging, clarification on adhesives used, confirmation of applicability of correspondences regarding biocompatibility sent for.G100141, clarification on particulates test fixture, and confirmation of proposed shelf life duration.
- 11/9/10 email—sponsor provided administrative documents needed due to the conversion from a PMA to a 510(k).
- 9/29/10 email—sponsor provided clarifications regarding test samples used for biocompatibility testing (referenced G100141 but confirmed to be applicable to the subject submission 11/24/10)
- 9/2/10 and 9/13/10—telecon regarding colorants and follow up email with minutes
- 8/19/10 email—feedback regarding number of inflations for particulates testing
- 8/16/10 telephone call—provided feedback regarding:
    - 20C for room temperature is not conservative enough
    - Need for particulates testing on aged samples, using the ASTM F2394 x2.4 fixture or equivalent
    - Clarification on why colorant information is being requested

XVII. Recommendation: Substantially Equivalent (SE)

Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty Catheter
Regulatory Class: Class II
Product Code: LOX

Katharine Fronczak 1/7/11

Katharine Fronczak, MS
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ODE / CDRH / FDA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) and (b)(5) Inter-Agency

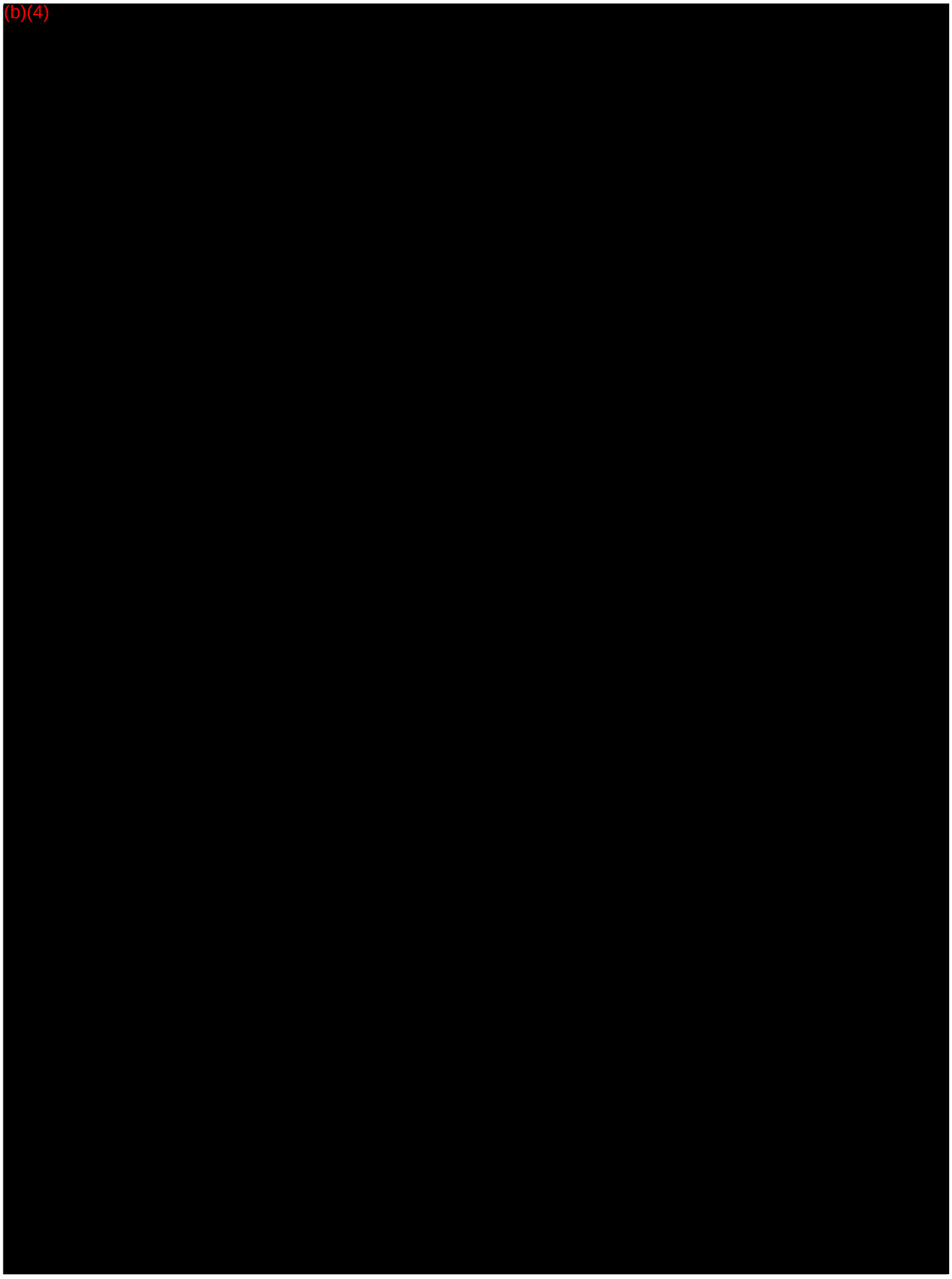
(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

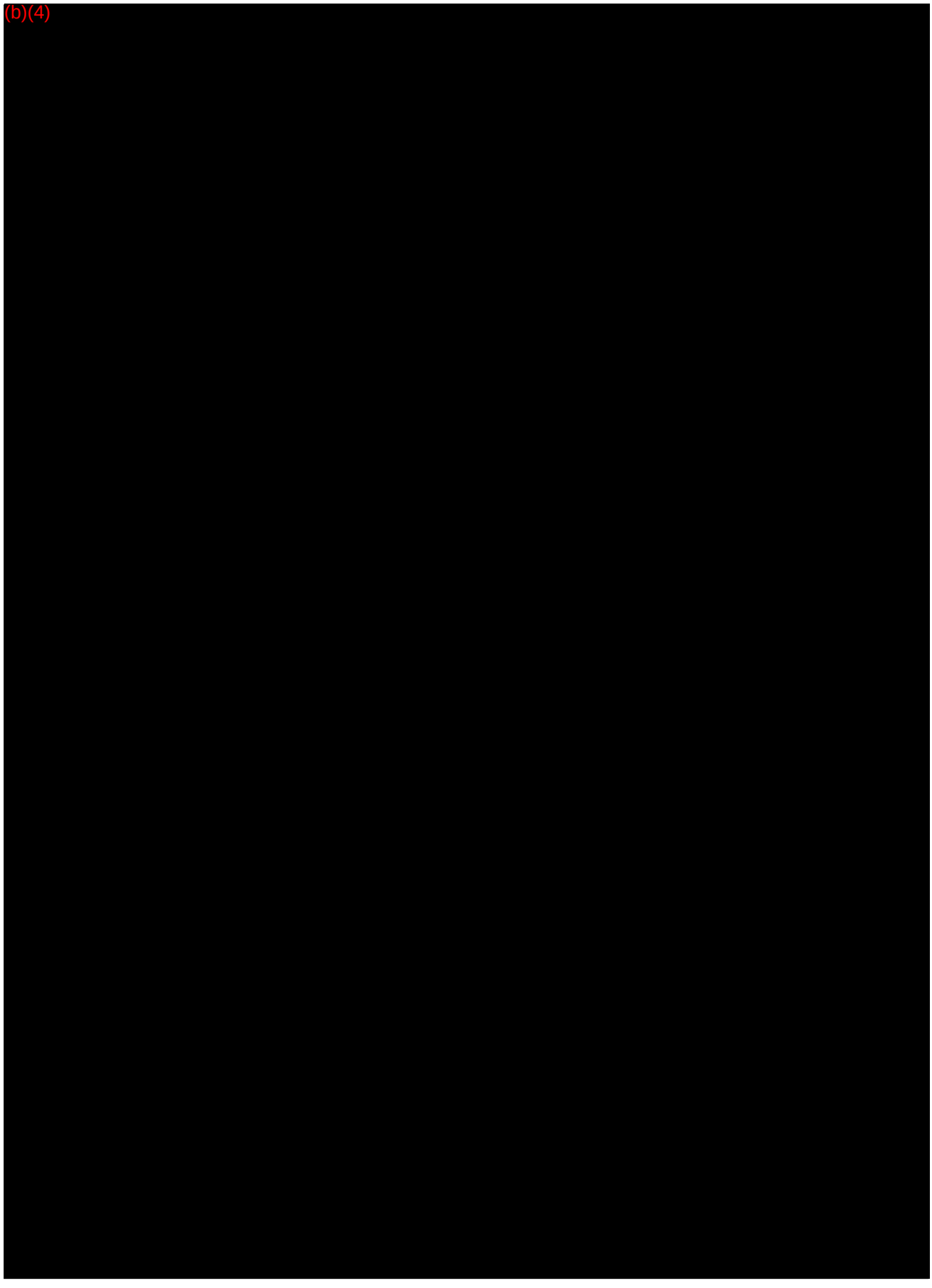
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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and cannot be detected in deeper stratum corneum layers, the human epidermis and dermis.
[Schulz J et al; Adv Drug Del Rev 54 (Supp 1): S157-S163 (2002)] **PEER REVIEWED**

Manufacturers :
Dyesol, Australia (Developing dye-sensitized solar cells (Gratzel cells) from nano-sized **titanium dioxide;** reports cells have 12: efficiency under some conditions
[Nanofrontiers. Nanotechnology: Energizing the Future. Iss 3, Fall, 2008. Washington DC: Woodrow Wilson International Center for Scholars. Available from, as of Nov 19, 2008: http://www.nanotechproject.org/process/assets/files/7045/nanofrontiers3energy.pdf] **PEER REVIEWED**

Major Uses :
Nanometer-scale particles ... (diameter 50 nm or less) /are/ a sought-after UV-blocking additive for sunscreens and cosmetics ... varnishes for the preservation of wood, textile fibers, and packaging films /**Titanium dioxide/**
[Shelley SA; p. 74 in Nanotechnology: Environmental Implications and Solutions., Theodore L, Kunz RG, eds., New York, NY: John Wiley & Sons, Inc. (2005)] **PEER REVIEWED**

Major Uses :
Demonstrate catalytic, photocatalytic and electrical properties ... possible applications such as the development of self-sanitizing tiles for restaurants and hospitals, and catalytic coatings on glass that catalyze the decomposition of organic buildup /**Titanium dioxide/**
[Shelley SA; p. 74 in Nanotechnology: Environmental Implications and Solutions., Theodore L, Kunz RG, eds., New York, NY: John Wiley & Sons, Inc. (2005)] **PEER REVIEWED**

Major Uses :
Use of nanosized ... powders... in photoelectrochemical solar cells and various types of improved thermal coatings for corrosion protection ...various polymer composites to yield a product with a tunable refractive index and improved mechanical properties for photonic and electronic applications ... attractice building block for optical network component applications /**Titanium dioxide/**
[Shelley SA; p. 74 in Nanotechnology: Environmental Implications and Solutions., Theodore L, Kunz RG, eds., New York, NY: John Wiley & Sons, Inc. (2005)] **PEER REVIEWED**

Major Uses :
Micrometer-sized TiO2 powders are widely used in surface coating, paper and plastic applications, and as a filler and whitening agent. /**Titanium dioxide/**
[Shelley SA; p. 74 in Nanotechnology: Environmental Implications and Solutions., Theodore L, Kunz RG, eds., New York, NY: John Wiley & Sons,

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Inc. (2005)] **PEER REVIEWED**

Major Uses :

Titanium dioxide has been used as a sun-blocking pigment in sunscreens for decades; in the mid-1990s advances in nanotechnology permitted the size of the pigments to be reduced to below 100 nm. Similar advances were also applied to a different material, zinc oxide, and today it is estimated that 30% of the sunscreens sold commercially contain these *inorganic nanoparticles*. By shrinking the size of sunscreen pigments, manufacturers generate products that can be applied very smoothly and appear clear to the eye.

[Colvin VL; Nanomaterials and Risk: Appropriate Use of the Technical Data. Delivered on October 10, 2006 at the Public Meeting on Nanotechnology Materials in FDA Regulated Products, Bethesda, Maryland, by D. Berube.] **PEER REVIEWED**

Human Toxicity Excerpts :

/OTHER TOXICITY INFORMATION/ This paper proposed a model-based approach to assess inhalation risk levels to manufacturing workers in **titanium dioxide** (TiO2) production factories. The risk level-based analytical schemes were present for investigations of job-related airborne nano/fine TiO2 dust exposures. A Hill model was used to reconstruct dose-response function based on data from rats exposed by chronic inhalation to poorly soluble fine and nanosized particles. A physiologically based lung model was used to predict surface area-based TiO2 burdens in alveolar surface and interstitial granuloma, respectively. The exposure effect was characterized by polymorphonuclear leukocytes (PMN) elevation effect on lung surface and lung tumor proportion on interstitium. Combining laboratory, field, and modeling results, two major findings were proposed to the current epidemiological studies: (i) the estimated median effective surface area-based TiO2 lung burden (EC50) for PMN elevation effect is 0.11 sq m/g lung (95% CI: 0.04-0.2) and EC50 for lung tumor proportion is 1.15sq m/g lung (95% CI: 0.65-1.89) and (ii) the estimates of risk curves are the pivotal results for public policy. The results demonstrate that packers in US factories have approximately 85.77 fold (95% CI: 63.84-94.33) of standard PMN counts of 10+6, whereas 86.97 fold (95% CI: 66.72-94.54) for surface treatment workers in EU factories at risk of 0.5. The lung had approximately 45% (95% CI: 15%-54%) tumor proportion for packers in US factories, whereas 48.19% (95% CI: 20-53.79%) for surface treatment workers in EU factories at risk of 0.5. The findings point out that dry/wet treatment and ore handlers in US and maintenance mechanics in EU factories were unlikely to pose substantial lung cancer risks.

[Liao CM et al; Sci Total Environ 407 (1): 165-77 (2008)] **PEER REVIEWED** PubMed Abstract

Non-Human Toxicity Excerpts :

/GENOTOXICITY/ **Titanium dioxide** (TiO(2)) ***nanoparticles*** have been shown to be ***genotoxic*** to cells exposed to ultraviolet A (UVA) radiation. Using the technique of electron spin resonance (ESR) spin trapping, /it was/ confirmed that the primary

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damaging species produced on irradiation of TiO(2) nanoparticles is the hydroxyl (OH) radical. ... This technique /was applied/ to TiO(2)-treated fish and mammalian cells under in vitro conditions and observed the additional formation of carboxyl radical anions (CO(2)(-)) and superoxide radical anions (O(2)(-)). This novel finding suggests a hitherto unreported pathway for damage, involving primary generation of OH radicals in the cytoplasm, which react to give CO(2)(-) radicals. The latter may then react with cellular oxygen to form O(2)(-) and genotoxic hydrogen peroxide (H(2)O(2)).
[Dodd NJ, Jha AN; Mutat Res 660 (1-2): 79-82 (2009)] **PEER REVIEWED** PubMed Abstract

Non-Human Toxicity Excerpts :
/GENOTOXICITY/ ... The underlying mechanism of **titanium dioxide** ***nanoparticles*** (nano-TiO2) induced cytotoxicity in peripheral blood lymphocytes /was investigated/. We examined the genotoxic effects of nano-TiO2 in lymphocytes using alkaline single-cell gel electrophoresis (Comet) and cytokinesis-block micronucleus (CBMN) assays. Lymphocytes treated with nano-TiO2 showed ***significantly increased micronucleus formation and DNA breakage.*** Western-blot analysis to identify proteins involved in the p53-mediated response to DNA damage revealed the accumulation of p53 and activation of DNA damage checkpoint kinases in nano-TiO2-treated lymphocytes. However, p21 and bax, downstream targets of p53, were not affected, indicating that nano-TiO2 does not stimulate transactivational activity of p53. The generation of reactive oxygen species (***ROS***) in nano-TiO2-treated cells was also observed, and N-acetylcysteine (NAC) supplementation inhibited the level of nano-TiO2-induced DNA damage. Given that ROS-induced DNA damage leads to p53 activation in the DNA damage response, the results suggest that nano-TiO2 induces ROS generation in lymphocytes, thereby activating p53-mediated DNA damage checkpoint signals.
[Kang SJ et al; Environ Mol Mutagen 49 (5): 399-405 (2008)] **PEER REVIEWED** PubMed Abstract

Non-Human Toxicity Excerpts :
/ALTERNATIVE and IN VITRO TESTS/ ...The cellular effects of ambient ultrafine particles /were compared/ with manufactured **titanium dioxide** (TiO2), carbon black, fullerol, and polystyrene (PS) nanoparticles (NPs). The study was conducted in a phagocytic cell line (RAW 264.7) that is representative of a lung target for NPs. Physicochemical characterization of the NPs showed a dramatic change in their state of aggregation, dispersibility, and charge during transfer from a buffered aqueous solution to cell culture medium. Particles differed with respect to cellular uptake, subcellular localization, and ability to catalyze the production of reactive oxygen species (ROS) under biotic and abiotic conditions. Spontaneous ROS production was compared by using an ROS quencher (furfuryl alcohol) as well as an NADPH peroxidase bioelectrode platform. Among the particles tested, ambient ultrafine particles (UFPs) and cationic PS nanospheres were capable of inducing cellular ROS production, GSH depletion, and toxic oxidative stress. This toxicity involves mitochondrial injury through increased calcium uptake and structural organellar damage. Although active under abiotic conditions, TiO2 and fullerol did not induce toxic oxidative stress. While increased TNF-alpha production

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could be seen to accompany UFP-induced oxidant injury, cationic PS nanospheres induced mitochondrial damage and cell death without inflammation. In summary, we demonstrate that ROS generation and oxidative stress are a valid test paradigm to compare NP toxicity. Although not all materials have electronic configurations or surface properties to allow spontaneous ROS generation, particle interactions with cellular components are capable of generating oxidative stress.
[Xia T et al; Nano Lett 6 (8): 1794-807 (2006)] **PEER REVIEWED**
PubMed Abstract

Non-Human Toxicity Excerpts :
/ALTERNATIVE and IN VITRO TESTS/ ... The study evaluated the acute toxic effects of ***metal/metal oxide nanoparticles*** ... using the in vitro ***rat liver derived cell line*** (BRL 3A). Different sizes of nanoparticles such as silver (Ag; 15, 100 nm), molybdenum (MoO(3); 30, 150 nm), aluminum (Al; 30, 103 nm), iron oxide (Fe(3)O(4); 30, 47 nm), and **titanium dioxide** (TiO(2); ***40 nm)*** were evaluated for their potential toxicity. ... The toxicity of relatively larger particles of cadmium oxide (CdO; 1 um), manganese oxide (MnO(2); 1-2 um), and tungsten (W; 27 um) /was assessed/ to compare the cellular toxic responses with respect to the different sizes of nanoparticles with different core chemical compositions. For toxicity evaluations, cellular morphology, mitochondrial function (MTT assay), membrane leakage of lactate dehydrogenase (LDH assay), reduced glutathione (GSH) levels, reactive oxygen species (ROS), and mitochondrial membrane potential (MMP) were assessed under control and exposed conditions (24 hr of exposure). Results showed that ***mitochondrial function decreased significantly*** in cells exposed to Ag nanoparticles at 5-50 ug/mL. However, Fe(3)O(4), Al, MoO(3) and ***TiO(2)*** had no measurable effect at lower doses (10-50 ug/mL), while there was a significant effect at higher levels ***(100-250 ug/mL)***. ***LDH leakage*** significantly increased in cells exposed to Ag nanoparticles (10-50 ug/mL), while the other nanoparticles tested displayed LDH leakage only at higher doses ***(100-250 ug/mL)***. In summary the Ag was highly toxic whereas, MoO(3) moderately toxic and Fe(3)O(4), Al, MnO(2) and W displayed less or no toxicity at the doses tested. The microscopic studies demonstrated that nanoparticle-exposed cells at higher doses became abnormal in size, displaying cellular shrinkage, and an acquisition of an irregular shape. Due to toxicity of silver, further study conducted with reference to its oxidative stress. The results exhibited significant depletion of GSH level, reduced mitochondrial membrane potential and increase in ROS levels, which suggested that cytotoxicity of Ag (15, 100 nm) in liver cells is likely to be mediated through oxidative stress.
[Hussain SM et al; Toxicol in Vitro 19 (7): 975-83 (2005)] **PEER REVIEWED** PubMed Abstract

Ecotoxicity Excerpts :
/AQUATIC SPECIES/ A semi-static test system was used to expose rainbow trout to either a freshwater control, 0.1, 0.5, or 1.0 mg/L TiO2 nanoparticles (NPs) for up to 14 days. Exposure to TiO2 NPs caused some gill pathologies including edema and thickening of the lamellae. No major hematological or blood disturbances were observed in terms of red and white blood cell counts, hematocrit values, whole blood hemoglobin,

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and plasma Na+ or K+ concentrations. Tissue metal levels (Na+, K+, Ca2+ and Mn) were generally unaffected. However, some exposure concentration-dependent changes in tissue Cu and Zn levels were observed, especially in the brain. Exposure to TiO2 NPs caused statistically significant decreases in Na+K+-ATPase activity (ANOVA, $P < 0.05$) in the gills and intestine, and a trend of decreasing enzyme activity in the brain (the latter was not statistically significant). Thiobarbituric acid reactive substances (TBARS) showed exposure concentration-dependent and statistically significant (ANOVA or Kruskal-Wallis test, $P < 0.05$) increases (two-fold or more) in the gill, intestine and brain, but not the liver during exposure to TiO2 NPs compared to controls. TiO2 NP exposure caused statistically significant (ANOVA, $P < 0.05$) increases in the total glutathione levels in the gills, but depletion of hepatic glutathione compared to controls. Total glutathione levels in the brain and intestine were unaffected. Liver cells exposed to TiO2 NPs showed minor fatty change and lipidosis, and some hepatocytes showed condensed nuclear bodies (apoptotic bodies). Fish probably ingested water containing TiO2 NPs during exposure (stress-induced drinking) which may have resulted in some areas of erosion on the intestinal epithelium. Overall we conclude that **titanium dioxide** nanoparticles are not a major ionoregulatory toxicant, or hemolytic, at the concentration and exposure times used. Respiratory distress is a concern and sub-lethal toxicity involves oxidative stress, organ pathologies, and the induction of anti-oxidant defences, such as glutathione.
[Frederici G et al; Aquat Toxicol 84 (4): 415-30 (2007)] **PEER REVIEWED** PubMed Abstract

Ecotoxicity Excerpts :
/AQUATIC SPECIES/ ...**Titanium dioxide** (TiO2) and fullerene (C60) nanoparticles /were prepared/ by filtration in tetrahydrofuran or by sonication. Daphnia magna were exposed to the four solutions using U.S. Environmental Protection Agency 48-hr acute toxicity tests. Images of the particle solutions were recorded using transmission-electron microscopy, and the median lethal concentration, lowest-observable-effect concentration, and no-observable-effect concentration were determined. Exposure to filtered C60 and filtered TiO2 caused an increase in mortality with an increase in concentration, whereas fullerenes show higher levels of toxicity at lower concentrations. Exposure to the sonicated solutions caused varied mortality. Understanding the potential impacts of nanoparticles will help to identify the most appropriate nanotechnology to preserve the aquatic environment while advancing medical and environmental technology.
[Lovern SB, Klaper R; Environ Toxicol Chem 25 (4): 1132-7 (2006)] **PEER REVIEWED** PubMed Abstract

Ecotoxicity Excerpts :
/AQUATIC SPECIES/ ...This study ... assessed potential toxicity of two commercially used nanomaterials (NMs), **titanium dioxide** (TiO(2)) and quantum dots (QDs), using the unicellular green alga Chlamydomonas reinhartii as a model system. The response of the organism to NMs was assessed at physiological, biochemical, and molecular genetic levels. Growth kinetics showed that growth inhibition occurred during the first two to three days of cultivation in the presence of TiO(2) or QDs. Measurements of lipid

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peroxidation measurement indicated that oxidative stress of the cells occurred as early as 6 hr after exposure to TiO(2) or QDs. The transcriptional expression profiling of four stress response genes (sod1, gpx, cat, and ptox2) revealed that transient up-regulation of these genes occurred in cultures containing as low as *1.0 mg/L of* TiO(2) or 0.1 mg/ L of QDs, and the maximum transcripts of cat, sod1, gpx, and ptox2 occurred at 1.5, 3, 3, and 6 hr, respectively, and were proportional to the initial concentration of the NMs. As the cultures continued, recovery in growth was observed and the extent of recovery, as indicated by the final cell concentration, was dosage-dependent. QDs were found to be more toxic to Chlamydomonas cells than TiO(2) under the experimental conditions.
[Wang J et al; Chemosphere 73 (7): 1121-8 (2008)] **PEER REVIEWED**
PubMed Abstract

Therapeutic Uses :
Other currently approved nanoparticle-containing products: Sunscreens (containing **titanium dioxide** and zinc oxide nanoparticles which make the product appear transparent)
[Sadrieh N; FDA Considerations For Regulation Of NanomaterialContaining ProductsNakissa Sadrieh, Office of Pharmaceutical Science, CDER, FDA.] **PEER REVIEWED**

Emergency Medical Treatment :

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The following Overview, *** **TITANIUM DIOXIDE** ***, is relevant for this HSDB record chemical.

Life Support:

- This overview assumes that basic life support measures have been instituted.

Clinical Effects:

0.2.1 SUMMARY OF EXPOSURE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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0.2.1.1 ACUTE EXPOSURE

A) **Titanium dioxide** is practically nontoxic and is generally regarded to be biologically inert. **Titanium dioxide** appears to be innocuous in all but the heaviest dust exposures. Even then, the only consistent effect (irritation) seem to be mild.

0.2.3 VITAL SIGNS

0.2.3.1 ACUTE EXPOSURE

A) In heavy dust exposure, cough and dyspnea may be seen. Effects are usually short-lived.

0.2.4 HEENT

0.2.4.1 ACUTE EXPOSURE

A) Heavy occupational exposures to the dust have been related to chronic rhinitis.

0.2.6 RESPIRATORY

0.2.6.1 ACUTE EXPOSURE

A) Concentrated fumes may irritate the respiratory tract. It is generally classified as a nuisance dust rather than an irritant.

B) Metal fume fever developed

C) Heavy occupational exposures to the dust have been related to chronic bronchitis and impaired pulmonary function with radiological findings resembling slight silicosis but without any fibrosis.

0.2.14 DERMATOLOGIC

0.2.14.1 ACUTE EXPOSURE

A) **Titanium dioxide** is virtually harmless on the skin and has been used therapeutically for skin diseases and in dressings for burned skin. One report lists it as a mild irritant after being applied for 3 days to human skin.

0.2.20 REPRODUCTIVE HAZARDS

A) No reproductive studies were found for **titanium dioxide**, in either humans or animals. Apparently titanium does not cross the placental barrier in humans, since levels in fetal tissue are undetectable.

0.2.21 CARCINOGENICITY

0.2.21.1 IARC CATEGORY

A) IARC Carcinogenicity Ratings for CAS13463-67-7 (IARC, 2004):

1) IARC Classification

a) Listed as: **Titanium dioxide**

b) Carcinogen Rating: 3

1) The agent (mixture or exposure circumstance) is not classifiable as to its carcinogenicity to humans. This category is used most commonly for agents, mixtures and exposure circumstances for which the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals. Exceptionally, agents (mixtures) for which the evidence of carcinogenicity is inadequate in humans but sufficient in experimental animals may be placed in this category when there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans. Agents, mixtures and exposure circumstances that do not fall into any

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other group are also placed in this category.

0.2.21.2 HUMAN OVERVIEW

A) **Titanium dioxide** is a questionable carcinogen when experimental carcinogenic, neoplastigenic, and tumorigenic data are evaluated. NCI carcinogenesis bioassay results were negative.

0.2.22 GENOTOXICITY

A) **Titanium dioxide** was inactive in the B. subtilis rec assay, a measure of primary damage to DNA. **Titanium dioxide** was inactive for inducing micronuclei in cultured Chinese hamster ovary cells; it was insoluble in the culture medium.

Laboratory:

A) No laboratory measures would be expected to be of value. If severe dyspnea occurs, monitor arterial blood gases.

B) A chest X-ray may establish titantium dioxide accumulation in patients with long term exposure and dyspnea.

Treatment Overview:

0.4.2 ORAL EXPOSURE

A) **Titanium dioxide** is minimally toxic. GI decontamination methods after ingestion are not required. No treatment is required after ingestion. Absorption is small, and most **titanium dioxide** will be eliminated in the feces.

0.4.3 INHALATION EXPOSURE

A) INHALATION: Move patient to fresh air. Monitor for respiratory distress. If cough or difficulty breathing develops, evaluate for respiratory tract irritation, bronchitis, or pneumonitis. Administer oxygen and assist ventilation as required. Treat bronchospasm with inhaled beta2 agonist and oral or parenteral corticosteroids.

0.4.4 EYE EXPOSURE

A) DECONTAMINATION: Irrigate exposed eyes with copious amounts of room temperature water for at least 15 minutes. If irritation, pain, swelling, lacrimation, or photophobia persist, the patient should be seen in a health care facility.

0.4.5 DERMAL EXPOSURE

A) OVERVIEW

1) DECONTAMINATION: Remove contaminated clothing and wash exposed area thoroughly with soap and water. A physician may need to examine the area if irritation or pain persists.

Range of Toxicity:

A) ESTIMATED LETHAL ORAL HUMAN DOSE - > 1 quart.

B) Ingesting one pound produced no ill effects in one human case.

[Rumack BH POISINDEX(R) Information System Micromedex, Inc., Englewood, CO, 2010; CCIS Volume 146, edition expires May, 2010. Hall AH & Rumack BH (Eds): TOMES(R) Information System Micromedex, Inc., Englewood, CO, 2010; CCIS Volume 146, edition expires May, 2010.] **PEER REVIEWED**

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(b)(4) and (b)(5) Inter-Agency

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Food and Drug Administration

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1886/F1886M-09 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-288		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1886/F1866M-09 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F720 - 2008 Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-123	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations *in the summary report* table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F720 - 2008 Standard *Practice for Testing* Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

No deviations or exclusions.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

ASTM F756:2008 Standard Practice for Assessment of Hemolytic Properties of Materials

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-154		
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials

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FDA Recognition number [3] # 14-283		
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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/ASTM/ISO 10993-10:2002 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hyperse

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-87		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance *criteria*? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/ASTM/ISO 10993-10:2002 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hyperse

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/ASTM/ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 2-118		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/ASTM/ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 2-98		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Categorization by nature of body contact	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exclusion of Sections 4.2.2, 4.2.4, 4.2.3(a), and 4.2.3(b)

DESCRIPTION

This section categorizes product by nature of contact with body.

JUSTIFICATION

These devices are categorized by Section 4.2.3(c) - an external communicating device in contact wtih circulating blood.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Categorization by duration of contact	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exlucsion of Section 4.3(b) and 4.3(c)

DESCRIPTION

This section categorizes product by duration of patient contact.

JUSTIFICATION

These devices are categorized by Section 4.3(a) - limited exposure device whose contact with the body is less than 24 hours.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2	Initial evaluation tests	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exlusion of Sections 5.2.7, 5.2.8, and 5.2.9

DESCRIPTION

These sections do not apply to PTCA catheter use.

JUSTIFICATION

These devices are used less than 24 hours and are not implanted, therefore, excluded sections do not apply.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1:2003 Biological evaluation of medical devices – Part 1: Evaluation and testing

COMFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.3	Supplementary evaluation tests	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED
Exclusion of Sections 5.3.2 through 5.3.5

DESCRIPTION
These sections are not applicable to PTCA catheters.

JUSTIFICATION
These devices are not intended for long term use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/ASTM/ISO 10993-12:2007 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 2-135		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the *standard*?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any *exclusions from the standard*? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/ASTM/ISO 10993-12:2007 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-4:2002 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-4:2002 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

No deviations or exclusions.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/ASTM/ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 2-153		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/ASTM/ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and *adequately justified as appropriate* for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethyelne oxide sterilization residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-279		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	Categorization of devices	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

The category "Limited Exposure" was selected for the testing of these devices.

DESCRIPTION

The "Limited Exposure" category is for devices whose cummulative single, multiple or repeated use or contacct is up to 24 hrs.

JUSTIFICATION

These devices are single use with cumulative contact of less than 24 hours.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Determination of EO and ECH residuals	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Conformance using the "simulated use extraction" option

DESCRIPTION

Simulated use extraction option was selected.

JUSTIFICATION

Extraction time of simulated use option is approximately 2 to 3 times greater than patient exposure time.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Product release	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Dissipation curves for EO residuals are not established

DESCRIPTION

Release of product is based on EO residual data.

JUSTIFICATION

Amount of residuals determined are at least 10X below resdidual limits at 0 hours after sterilization.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and re

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-228		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and re

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex A	Determination of lethal rate of the sterilization process - BI/bioburden	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

Exlusion of section related to BI/bioburden approach for determination of lethality rate of sterilization process.

DESCRIPTION

Multiple options provided for completing the process lethality determination.

JUSTIFICATION

Annex B, overkill approach, was used for process lethality determination.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-193	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard *used included in the* 510(k)? If no, complete a summary report table.	☐	☑
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
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Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.1	Materials and preformed sterile barrier systems	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exclusion of Section 5.1.10

DESCRIPTION

This section provides requirements for reusable containers.

JUSTIFICATION

These devices do not include reusable containers, therefore, this section does not apply.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2	*Microbial barrier properties*	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exclusion of Section 5.2.3

DESCRIPTION

This section requires porous materials to provide a microbial barrier.

JUSTIFICATION

These devices use peel pouch packaging which is non-porous, therefore, this section does not apply.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2	Design	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exclusion of Section 6.2.4

DESCRIPTION

This section requires components of fluid path closure to be identified.

JUSTIFICATION

These devices do not have an applicable sterile fluid-path, therefore, this section does not apply.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and a

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-194		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and a

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Use of reusable sterile barrier systems	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *.

Exclusion of Section 7

DESCRIPTION

This section provides requirements for reusable sterile barrier systems.

JUSTIFICATION

These devices do not include reusable sterile barrier systems, therefore, this section does not apply.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Sterile fluid-path packaging	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exclusion of Section 8

DESCRIPTION

This section contains requirements for fluid-path packaging.

JUSTIFICATION

These devices do not have sterile fluid path packaging, therefore, this section does not apply.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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STANDARD TITLE [1]

USP32, <151> Pyrogen Test, 2009

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-268		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at *www.fda.gov/cdrh/guidance.html*

PSC Graphics (301) 443-6090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
USP 32, <151> Pyrogen Test, 2009

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
Requirements of standard were met.

DESCRIPTION
No deviations or exclusions.

JUSTIFICATION
No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP 32, <161> Transfusion and Infusion Assemblies and Similar Medical Devices, 2009

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-269		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Guideline on Validation of the LAL Test as an End-product Endotoxin Test for Human Parenteral Drugs,

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 130

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

USP 32, <161> Transfusion and Infusion Assemblies and Similar Medical Devices, 2009

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements of standard were met.

DESCRIPTION

No deviations or exclusions.

JUSTIFICATION

No deviations or exclusions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Form Approved: OMB No. 0910-0120: Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP 32, <85> Bacterial Endotoxins Test (2009)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-267		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Guideline on Validation of the LAL Test As An End-Product Endotoxin Test for Human and Animal Pare

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

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(b)(4) and (b)(5) Inter-Agency

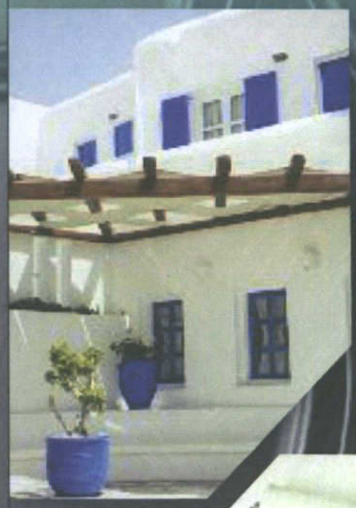
Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

CRISTAL Global كريستل العالمية

TiONA® 595

FOR COATINGS

The Global Performer







141

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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CONTROLLED PARTICLE SIZE

The particle size of Tiona 595 is carefully controlled using Cristal Global's proprietary, chloride-process technology. This maximizes light scattering, which provides key performance benefits in opacity and tinting strength.

TIONA® 595

Best In Design

The efficient use of titanium dioxide is one of the key considerations in formulating any coatings product. Tiona 595 sets a new benchmark for titanium dioxide products as it provides exceptional all-round performance.

The global research expertise and superior manufacturing capabilities of Cristal Global have been combined to offer a pigment of unparalleled performance.

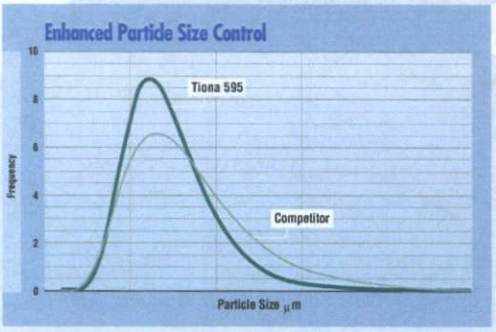
In designing Tiona 595, the features of our existing high performance TiO_2 products have been combined and enhanced to deliver a global product that has an outstanding range of attributes.

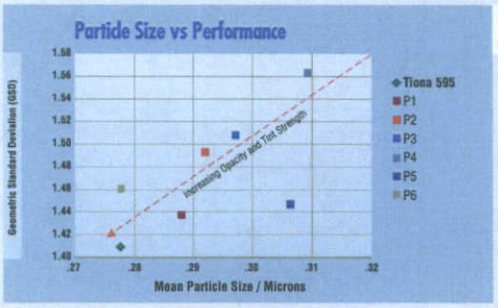
Figure 1 compares the particle size distribution of Tiona 595 with a competitive product. Figure 2 shows the superior performance of Tiona 595 as depicted by its optimized mean particle size and low standard deviation.

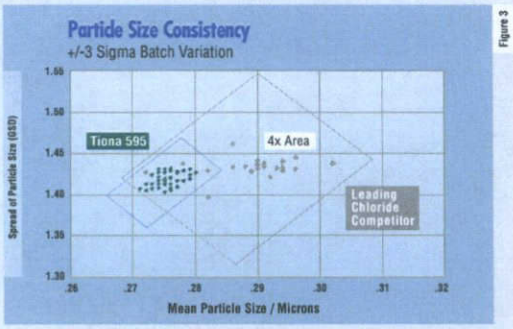
Optimized particle size also minimizes the number of oversized particles, which impair gloss and generate greater haze. Tiona 595 is therefore well suited for applications requiring excellent gloss and showroom appeal.

While superior particle size distribution is paramount in today's quality-conscious market, consistency is also a critical aspect. Figure 3 demonstrates Cristal Global's exceptional process control in the production of Tiona 595.









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ADVANCED SURFACE TREATMENT

An innovative surface treatment is used to make Tiona 595 suitable for many applications.

The treatment technology is based on a combination of alumina and zirconia surface treatments that make Tiona 595 compatible in both water- and solvent-based coatings systems. The advanced treatment technology minimizes flocculation thus ensuring excellent optical performance in many formulations.

The addition of an organic polyol onto the pigment surface enhances the dispersion and bulk flow properties of Tiona 595.

In combination with the process technology, the treatment is designed to give a high level of durability making Tiona 595 suitable for a diverse range of products.

Best in Performance

The superior design of Tiona 595 provides many performance advantages for the formulator of high performance coatings.

The combination of optimized particle size and novel surface treatment is responsible for the superior tinting strength and opacity benefits of Tiona 595 (Figures 4 and 5).

The excellent durability performance in terms of gloss retention and chalking resistance is demonstrated in an acrylic isocyanate formulation (Figures 6 and 7).



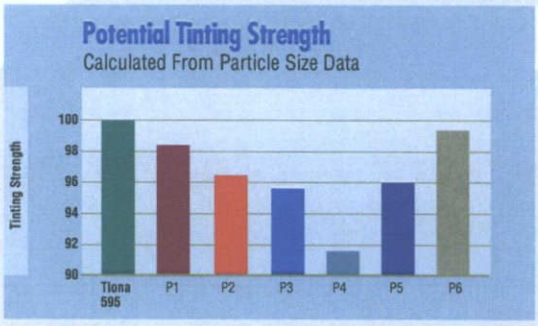


Figure 4

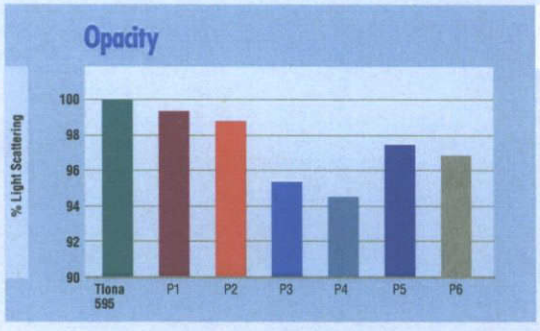


Figure 5

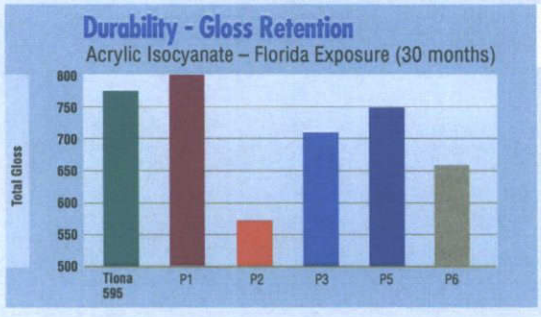


Figure 6

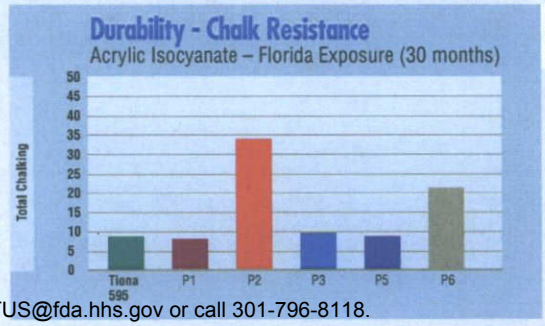


Figure 7

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SUPERIOR VALUE

The superior value of Tiona 595 allows paint manufacturers to achieve technology advances and formulate cost effectively.

The Global Performer

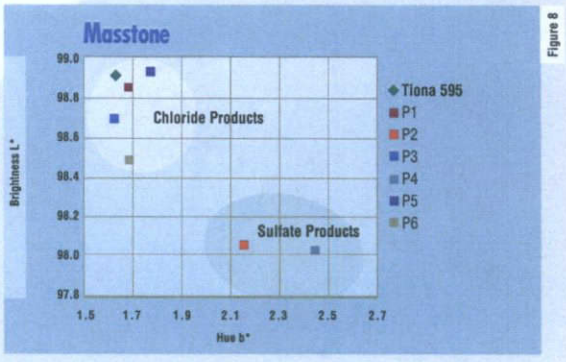
The unique combination of performance properties makes Tiona 595 a technological champion in titanium dioxide, providing a superior level of performance for a diverse range of formulations.

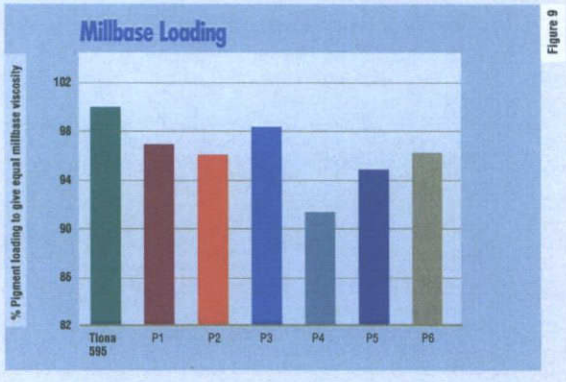
Tiona 595 provides an improved color unsurpassed by any other TiO_2 product in most formulations (Figure 8). Tiona 595 retains high brightness and demonstrates excellent color stability in both air-drying and stoving systems.

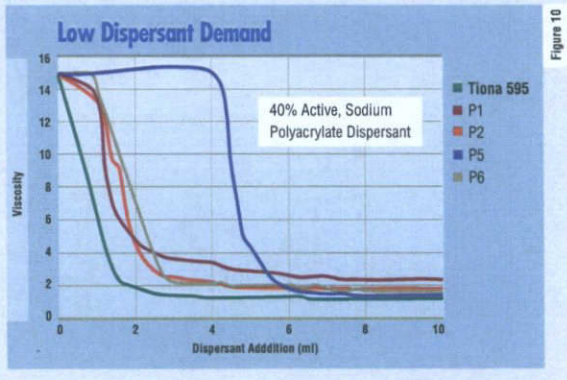
High millbase loadings can be achieved with Tiona 595 giving the potential for increased productivity in the coatings manufacturing process (Figure 9).

A low dispersant demand is required to achieve efficient, stabilized coatings systems. This feature can reduce costs and minimize any excess ionic species thus reducing water and corrosion sensitivity of paint films using Tiona 595 (Figure 10).









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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INNOVATIVE TECHNOLOGY

Tiona 595 is an innovative pigment designed to give exceptional performance in a wide range of demanding coatings systems.

TIONA® 595

KEY FEATURES

Exceptional opacity
Outstanding tinting strength
Superior color and color stability
Excellent durability
Excellent gloss
Fast and efficient dispersion
High millbase loadings
Low dispersant demand

APPLICATIONS

Decorative Coatings
- Interior & Exterior
- Water- & Solvent-based

General Industrial Coatings
Automotive, OEM & Refinish
Powder Coatings
Marine and Protective Coatings
Primers & Undercoats
Low VOC/High Solid Formulations

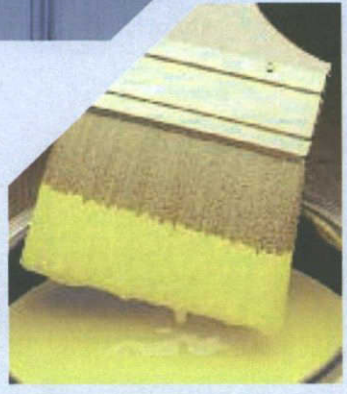
TYPICAL PROPERTIES

Crystal Form	100% Rutile
TiO_2 Content	95%
Oil Absorption	19g/100g
pH (10% suspension)	7.5
Specific Gravity	4.1
Density	34.2 lbs./gal

OFFICIAL STANDARDS

Tiona 595 conforms to:
BS EN ISO 591-1:2000 Type R2
ASTM D 476-00 Type VII
ECOIN/ACOIN: TiO_2
Is listed under EINECS number 236-675-5
CAS No. 13463-67-7
Color Index 77891, Pigment White 6





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This document does not constitute a specification. Product Specifications are available on request.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

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(b)(4) and (b)(5) Inter-Agency

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name ERICA TAKAI

Subject: 510(k) Number K103110

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Ashley B. Boam (Branch Chief) ICDB (Branch Code) 12/2/10 (Date)

Final Review: _____ (Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Premarket Notification [510(k)] Review
Traditional/Abbreviated

K103110

Date: December 1, 2010
To: The Record
From: Erica Takai, PhD

Office: ODE
Division: DCD/ICDB

510(k) Holder: Abbott Vascular
Device Name: Mini TREK RX, TREK RX, Mini TREK OTW, and TREK OTW Dilation Catheter
Contact: Suzanne Redman
Principal Regulatory Affairs Associate
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Review Team:
- Jennifer Goode, DCD/PVDB, Biocompatibility Reviewer (mainly for colorant issues)
- Hoan My Do Luu, OSEL/DCMS, Chemist (for colorant elution issues)
- Rosalie Elespuru, OSEL/DB, Toxicologist (for colorant risk assessment)
- Erica Takai, DCD/ICDB, Lead Reviewer

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Abbott TREK and Mini TREK Rapid Exchange (RX) and Over-the-Wire (OTW) Dilation Catheters into interstate commerce.

This 510(k) was originally a PMA supplement (P810046/S235; see memo for details), which was down classified to a class II 510(k) on October 8, 2010. The current submission is a response to a major deficiency letter sent August 9, 2010. There are still outstanding deficiencies regarding biocompatibility (including color additives information) and bench testing, so additional information will be requested. The current submission also adds the OTW version of the device for which information was not previously submitted. The balloon sizes are within the range of currently approved PTCA catheters. There is currently a conditionally approved IDE G100141 for the Abbott MINI TREK 1.20mm balloon size, which is essentially the same as the MINI TREK device in the current submission, but with a smaller balloon.

Since the conversion to a 510(k) occurred after the sponsor submitted their response (A002), the administrative documents required for a 510(k) were provided via email (11/9/10).

II. Administrative Requirements

	Yes	No/ Inadequate	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		

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(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

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(b)(4) and (b)(5) Inter-Agency

[redacted]

IV. Indications for Use

The indications for use for the TREK™ RX and MINI TREK™ RX Coronary Dilatation Catheters are as follows:

> The TREK™ RX and MINI TREK™ RX Coronary Dilatation Catheters are indicated for: (a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion; (b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction; (c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

The indications are similar to that of the VOYAGER RX Coronary Dilatation Catheter (P810046/S216):

> The VOYAGERTM RX Coronary Dilatation Catheter is indicated for: (a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion, (b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction, (c) balloon dilatation of a stent after implantation. (Testing included the following Guidant stents: MULTI-LINK: PIXEL®, and PENTA® / ZETA® Coronary Stent Systems.)

The main difference is in the stents identified for post-dilation (balloon size vs identifying specific stents). There are currently no stents (bare or drug eluting) that are indicated for a reference vessel diameter <2.25mm, and the indication states that the post dilation use applies only to 2.0-5.0mm models only. Accordingly, in-stent bench tests (fatigue and burst) were performed on 2.0mm or larger sizes. The indications are acceptable.

V. Predicate Device Comparison

The TREK RX and MINI TREK RX are similar in deign, material and indications to the currently approved VOYAGER RX Coronary Dilatation Catheter (P810046/S216, approved June 18, 2004). The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are similar in design, materials, and indications to the currently approved VOYAGER OTW Coronary Dilatation Catheter (P810046/S214, approved March 12, 2004). Additionally, the distal portion of the catheter from the mid-lap joint to the tip, including all balloon diameters and lengths, is identical to the same distal portion of the TREK RX and MINI TREK RX Coronary Dilatation Catheters.

The new design of the TREK/MINI TREK RX and OTW Coronary Dilatation Catheters include the following:

- A Pebax balloon with a Rated Burst Pressure (RBP) of 14 atm. Pebax 70D is used for the 1.50 mm through 2.00 mm balloons. A co-extrusion of Pebax 70D over Pebax 63D is used for the 2.50 mm through 5.00 mm balloons.

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- A single piece hypotube design across all balloon sizes that includes a redesigned guide wire notch. (only RX)
- A tip-through design where the soft tip is directly joined to the inner member under the balloon's distal taper.
- A Microglide coated inner member intended to improve device interaction between the guide wire and the catheter.
- The absence of glue joints. All joints are bonded using methods which do not involved the use of adhesives. (RX only; OTW has adhesives in the proximal bond see 11/24/10 email)

(b)(4) and (b)(5) Inter-Agency

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 168

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

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(b)(4) and (b)(5) Inter-Agency

[redacted]

VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.807.87 (e).

The labeling includes a prescription only symbol, and appropriate warnings regarding single use/not resterilizing or reusing. The labeling also includes a device description and indications statement which are appropriate. They also include a summary of the GUSTO II Direct PTCA Substudy of patients with ST segment elevated myocardial infarctions. This trial did not use the subject PTCA catheter. The directions in the IFU were generally clear and adequate. See deficiencies section below for issues related to missing inflation cycles and Rx symbol missing from the glossary. No compliance chart in IFU though in label.

VII. Sterilization/Shelf Life/Reuse

The same sterilization cycle is performed by the same sterilizer as the VOYAGER RX catheter (P810046/S216). The materials used for the subject catheters are similar (differences primarily in a different formulation of Pebax), and the lumen diameters are similar or larger to the VOYAGER RX. The sterile barrier used for the TREK and MINI TREK, both RX and OTW, are identical to the VOYAGER RX. Due to the similarity between the TREK/MINI TREK and the Voyager in materials, dimensions, and packaging, it is acceptable to leverage sterilization information.

1. Sterilant:	YES	NO

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) and (b)(5) Inter-Agency

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(b)(4) and (b)(5) Inter-Agency

[redacted]

This response is **acceptable**.

b &c. *CFR listings:*
Sponsor provided the requested information for part b, but for the exemption from batch certification per CFR (part c), Bayer and CFC have not responded and a request for this information was sent to the MAF holders via email (see Ms. Goode's 11/30/10 memo for details)

d. *Amounts:*
Sponsor/MAF holders provided this information (see Ms. Goode's 11/30/10 memo for details). This response is **acceptable**.

e. MSDS:
Some were still missing from CFC's white foil and a request for this information was sent to the MAF holders via email. (see Ms. Goode's 11/30/10 memo for details).

f. Risk Assessment:
Both Dr. Hoan My-Do Luu, and Dr. Rosalie Elespuru reviewed this colorant information and risk assessment. *While Dr. Elespuru did not agree with all of the scientific statements made by Abbott* Vascular in this risk assessment, she and Dr. Luu both agreed that additional information regarding these colorants (from a toxicity perspective) are not needed. Dr. Luu also reviewed the Table A6-5 regarding solubility of the various chemicals, and agreed that the risk of leaching is minimal. Ms. Goode indicated in her memo (11/30/10) that this response is **acceptable**.

g-i. Leaching study, CAP etc
These are not applicable/needed based on the risk assessment being acceptable (part f).

Deficiency:

3. For the colorant being used in the white foil proximal marker, please acknowledge your understanding that additional information is being requested of CFC International regarding their Type III DMF #17442 letter of authorization dated August 27, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

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4. For the aqua colorant being used in the RX Catheter Clip, please acknowledge your understanding that additional information is being requested of Clariant regarding their Type III DMF #10640 letter of authorization dated September 10, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

5. For the colorant being used in the purple colorant used in the side arm, please acknowledge your understanding that additional information is being requested of CFC International regarding their MAF#0353 letter of authorization dated August 26, 2010. The Master File Holder is being asked to submit this information interactively via email and once it is found to be sufficient, they will be asked to make an official submission to the master file.

Question 8. For nearly all bench tests performed, it was not clear how you determined the sample size needed for each test. For all bench tests, please clarify how you determined the sample size. For example, the number of samples tested for rated burst pressure should demonstrate 95% confidence and 99.9% reliability that the balloons will survive. If you determine that an insufficient number of samples were tested, please test additional samples. Please refer to our draft guidance Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters for more details regarding sample size recommendations for each test.
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070984.htm

Sponsor Response/ Reviewer Comments:
The sponsor states that sample size was determined based on one of 2 methods:

Statistical Rationale
- Rated Burst Pressure (RBP) – 95% confidence and 99.9% reliability (n=20 at t=0 and n=15 at 2 yrs per size)
- Minimum Balloon Burst Strength (In Stent) – 95% confidence and 99.9% reliability (n=20 at t=0 and n=15 at 2 yrs per size)
- Balloon Compliance Pressure– 95% confidence and 99.9% reliability (n=19 or 20 at t=0 and n=14 or 16 at 2 yrs)
- Balloon Fatigue– 95% confidence and 90% reliability (n=30)
- Balloon Fatigue (in stent)– 95% confidence and 90% reliability (n=30)

Scientific Rationale:
"For all remaining bench test performed, the number of samples was based on the acceptance criteria required to demonstrate that the design meets dimensional and functional specifications per the product specification. For these tests, the minimum sample size was selected based on requirements described in AV's internal operating procedure for Filing and Aging Testing which specifies a minimum sample size of 10 units per test group."

Using a six sigma approach (process capability to produce outputs within specification limits or Cpk), the sponsor set Cpk ≥ 1 which gives a reliability of ~≥ 99% for one-sided specifications, 95% confidence interval (alpha 0.05), and a 90/90 confidence and reliability and calculated n=9 for with these parameters. *The calculation provided appears to be correct, although it appears that the industry standard for six sigma approach is n=30 (and anything lower may be justified by Cpk analysis).*

This response is ***acceptable****.*

Question 9. In your Catheter Preparation test, it is not clear why you did not include the 4.0mm x 30mm size device for both baseline and aged device testing, since it is one of the largest diameter balloons with the longest length. In addition, it is unclear why you have tested a different size TREK RX device for your aged samples and baseline (un-aged) samples. Please repeat testing on aged 5.00mm x 15mm devices and on both aged and baseline 4.0mm x 30mm size devices, and provide a complete test report. Alternatively, please provide a scientific rationale for the device sizes tested.

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Sponsor Response: The sponsor clarifies that the balloon size does not affect the ability to prep the device because the balloon is held under negative pressure, effectively eliminating any volume of air within the balloon (prior to prep). The catheter shaft is identical across all balloon sizes, for TREK RX and MINI TREK RX. The catheter shaft internal dimensions affect the ability for the contrast to flow through the inter-lumen space during prep. One size balloon from each chassis configuration, for both baseline and aged samples, were tested to represent all sizes in the matrix.

Reviewer Comments: Given that other tests (crossing profile, inflation/deflation etc) assess related characteristics, this response is **acceptable**.

Question 10. In your Catheter Profile test, it appears you did not perform the Crossing Profile test on 4.0mm x 30mm size devices at baseline and after aging, although you have performed Refolded Profile testing on this device size. Please perform Crossing Profile testing on 4.0mm x 30mm size devices at baseline and after aging, or provide a scientific rationale for the omission of this device size. Similarly, it is unclear why the 2.00mm x 30mm size device, which is the largest diameter and longest balloon length MINI TREK device, was not subjected to Refold Profile testing after aging. Please perform Refold Profile testing on the 2.00mm x 30mm size devices and provide a complete test report, or provide a scientific rationale for the omission of testing using this device size.

Sponsor Response/ Reviewer Comments:
Sponsor states that the Crossing Profile was tested on the 5.00 mm x 15 mm balloon diameter for both the baseline and aging as it is the largest diameter and represents the largest crossing profile specification within the TREK RX product family. The product specification requirement for crossing profile on the 5.00 mm size is 0.048" maximum, and the sponsor states their label claims for 5F guide catheter compatibility based on 0.056" ID minimum guide catheters. Therefore, the 5.00 mm x 15 mm size is considered to bracket all sizes within the product family, including the 4.00 mm x 30 mm balloon diameter. *The sponsor only states "Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery" in their IFU and are not limiting to 5F guide catheters.*

Sponsor states that for aged devices, Refolded Balloon Profile was tested on the 4.00 mm x 30 mm and 5.00 mm x 15 mm because the 5.00 mm is the largest diameter that must be capable of pullback into a 6F guide catheter (15 mm balloon length is the longest balloon length available for the 5.00 mm balloon diameter) and the 4.00 mm balloon diameter is the largest diameter that must be capable of pullback into a 5F guide catheter. These were identified to therefore be the worst case. *Given that the refold profile is not a required test, and simulated use testing was performed as part of particulates testing, this portion of the response is* ***acceptable****.*

Deficiency:

1. Please address the following concerns regarding guide catheter compatibility:
    a. In your response to deficiency #10 regarding Crossing Profile, you indicate that your label claims 5F guide catheter compatibility based on 0.056" ID minimum guide catheters. However, your IFU currently only states "Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery" and are not limiting compatible accessories to 5F guide catheters. The labeling language regarding guide catheter selection is acceptable since you have identified the French size of the thickest part of each device size in your labeling (3.4Fr for all devices). However, it is unclear whether your testing sufficiently assesses the compatibility of the guide catheters expected to be used. Specifically, in response to deficiency #17f regarding Particulates testing (combined with simulated use testing), you have identified the accessory devices used in your testing but did not specify the accessory device sizes. Please provide this information.

Question 11. The rationale behind the device sizes selected for post-aged Balloon Fatigue testing was not clear. Please repeat Balloon Fatigue using aged samples of all "corner sizes" for both the MINI TREK and TREK catheters or provide a scientific justification for the sizes used for post-aged samples. Specifically, the 2.75mm x 30mm size does not appear to be a corner size, and this 2.75mm x 30mm size

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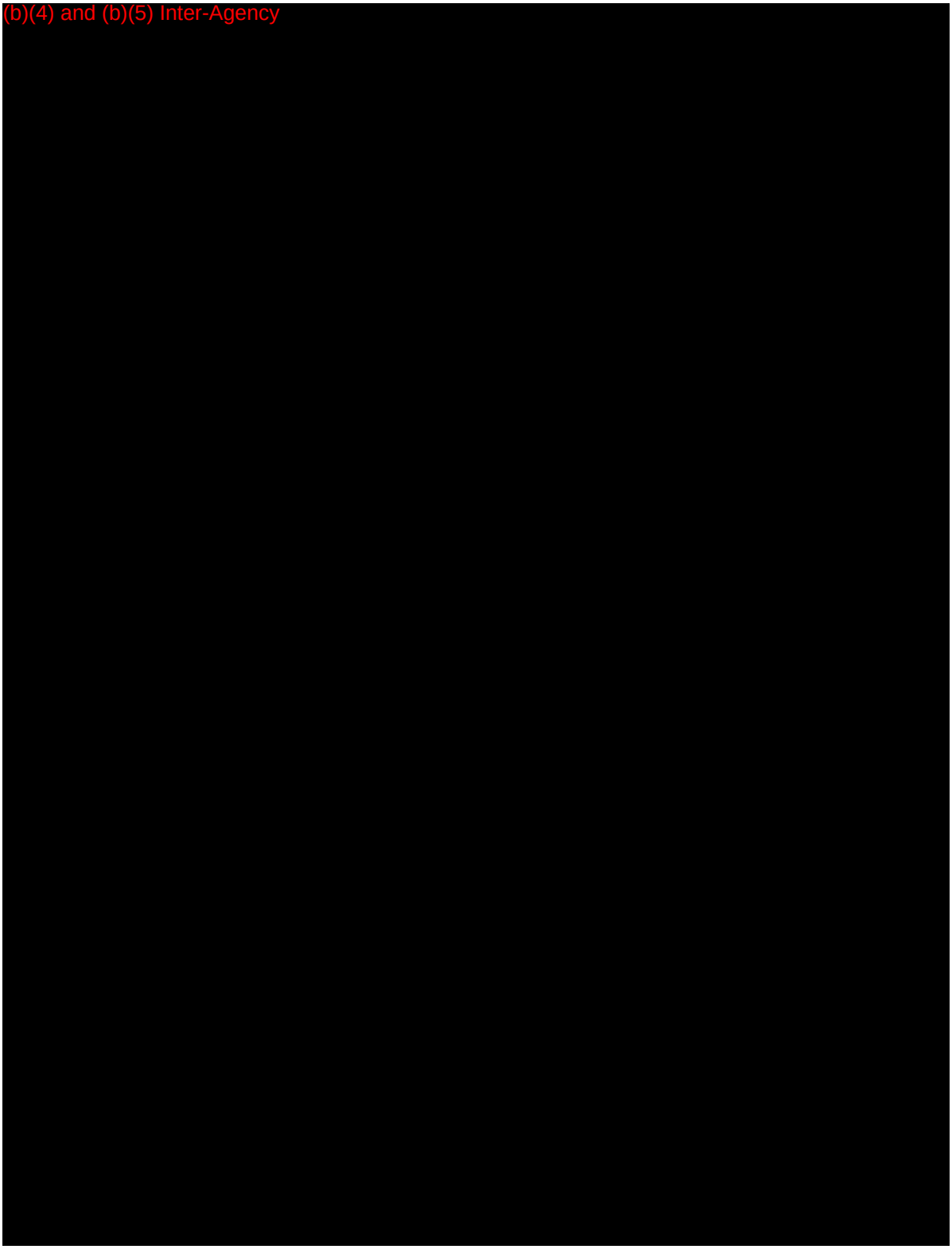
was not tested at baseline.

Sponsor Response:
The sponsor states that they performed baseline testing on all corner sizes for the TREK and MINI TREK, and provide the following rationale for choosing non corner sizes. They performed an engineering study to identify and select the post-aged sizes to be tested for balloon outputs to identify actual worst-case balloon diameters for each balloon design, MINI TREK (single layer, 1.50 mm – 2.00 mm) and TREK (co-extruded, 2.25 mm – 5.00 mm), to be tested for post-aged balloon outputs. This study evaluated balloon fatigue and balloon rupture for the shortest and longest lengths of each balloon diameter at baseline (clarified in 11/24/10 email). The shortest and longest lengths within each diameter were pooled for analysis. A minimum of 30 samples per diameter were evaluated.
From 11/24/10 email:

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(b)(4) and (b)(5) Inter-Agency



Sponsor states that while each size met all specifications, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters.

Reviewer Comments: The sponsor used 1.50 mm x 20 mm (Mini TREK, also tested at baseline) and 2.75 mm x 30 mm (TREK, not tested at baseline) for their aged device testing. In their engineering study to ID

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the worst case device for aging testing, the sponsor did perform balloon fatigue testing to 20 cycles for the 2.75x30mm size at baseline, and all samples passed. However, from this engineering study and the Balloon Rupture test provided in the P810046/S235, it is not clear that the 2.75 size is worse than the 5.0mm size devices.

Deficiency:

2. Please address the following concerns regarding the lack of testing using the 5.0x15mm device size for Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing:
    a. You have performed an engineering study using baseline samples to identify the worst case device size for the TREK and Mini TREK catheters (RPT2073031), which examined Balloon Fatigue (without a stent) and Balloon Rupture. It is unclear from this test report whether the 2.75mm balloon is indeed the worst case when compared to the 5.0mm balloons, in part because the data from the shortest (6mm) and longest (30mm) were pooled. You have also provided Balloon Rupture testing using devices determined to be worst case from your initial engineering study (p. 6-72 of P810046/S235). From the test data provided in your P810046/S235 submission, the 5.0x15mm and 5.0x12mm size devices had the lowest Rupture pressure and RBP at baseline, lower than that of the 2.75x30mm devices. Therefore, from the data presented, it is unclear whether the 2.75x30mm diameter devices used for post-aged testing is the worst case compared to one of the 5.0mm diameter devices. Please perform Balloon Fatigue (within and without a stent), Balloon Rupture, and Balloon Compliance testing on your worst case 5.0mm device size aged to your proposed shelf life, or provide additional data to support the 2.75x30 mm size as the worst case.
    b. You also noted in response to deficiency #13 regarding Balloon Rupture testing, that the data from the baseline 5.0x15mm devices give the appearance that this is the worst case size, but attribute this to lot-to-lot manufacturing variations. Since it appears that you have not perform Balloon Rupture testing on different lots for a given device size, we cannot conclude that differences observed between different sizes are due to different lots and not due to the device size. Please keep this in mind, should you chose to provide additional justification for testing the 2.75x30mm devices post-aging.

Question 12. Please address the following concerns regarding your Balloon Fatigue Within a Stent testing:

a. You did not perform this test using the 1.50mm x 6mm size (smallest diameter x shortest length) device at baseline or post-aging. Please repeat testing using 1.50mm x 6 mm size devices and provide a complete test report, or provide a scientific rationale for the omission of testing using this device size.

b. Please repeat testing using aged samples of all "corner sizes" for both the MINI TREK and TREK catheters or provide a scientific justification for the sizes used for post-aged samples. Specifically, the 2.75mm x 30mm size does not appear to be a corner size, and this size was not tested at baseline. While you state that "the size selection for aged product includes the diameters with the calculated lowest balloon rupture mean due to having the lowest calculated hoop strength per balloon material," it is not clear how this was determined. In addition, 5.0x12mm size baseline samples had 2 failures, for which the root cause could not be found. Therefore, the 5.0x12mm samples appear to be empirically the worst case and should also be tested post-aging.

c. Please clarify what size stents were used for each balloon size tested.

Sponsor Response/ Reviewer Comments:
a. Sponsor states that there are no 1.5mm diameter stents approved. The proposed indication associated with post-stent dilatation is applicable only to the 2.00 mm through 5.00 mm balloon diameters. There are 2.0mm diameter stents approved such as Abbott's Multi-Link 8 stent. *This response is **acceptable**.*

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b. *For the Mini TREK the 2.0mm diameter size tested is the only Mini TREK size that can be used in stent (post dilation indicated for 2-5mm balloons).* The sponsor references the same burst pressure/balloon rupture aging engineering study they performed in reference to Q11 above. Sponsor states that while *each size met all specifications*, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters, to justify the selection of these device sizes for aged device testing.

At baseline testing, the 5.00 mm x 12 mm had two samples which did not achieve the required 10 cycles for Balloon Fatigue Within a Stent testing. An additional 29 samples were added to the to the Balloon Fatigue Within a Stent testing, which satisfied the requirement of 10 repeated inflations with 95% confidence and 90% reliability. Sponsor states that since the 5.00 x 12 mm met the fatigue requirement for within a stent, the original worst case size selection is still valid. *I do not entirely agree with this statement given that when the same sample size was tested as other device sizes, the 5x12mm devices had 2 failures while other sizes had none. While additional testing to almost double the total sample size did demonstrate a passing result, this would indicate that the sample size to begin with may have been insufficient. It appears that the sponsor did perform burst pressure and fatigue (not in stent) testing, for 5.0x12mm sizes in the engineering study, but the data does not clearly demonstrate that even at baseline, that the 2.75mm is worst case.*

(b)(4) and (b)(5) Inter-Agency

[redacted]

Question 13. In your Balloon Rupture test, you did not include 2.00 x 30mm and 1.50 x 15mm devices although these sizes showed the lowest burst pressure at baseline. Please repeat Balloon Rupture testing including these device sizes and provide a complete test report. Please also provide a statistical comparison between the burst strengths of aged and baseline samples, and if there is a statistically significant decrease, please provide a scientific rationale as to why this decrease does not raise a safety concern.

Sponsor Response/Reviewer Comments: *Note that in the deficiency 1.5x15mm should have been 5.0 x15mm which the sponsor noted.*

The sponsor references the same burst pressure/balloon rupture aging engineering study they performed in reference to Q11 above. Sponsor states that while each size met all specifications, the 1.50 mm and 2.75 mm balloon sizes were selected as worst case on the basis of having the lowest calculated Rated Burst Pressure (RBP) across all diameters, to justify the selection of these device sizes for aged device testing. Abbott also acknowledges that the baseline data gives the appearance that the 2.00 mm x 30 mm and the 5.00 mm x 15 mm represent worst case sizes, but that based on the conclusions presented in the engineering study of aged balloons (above), this anomaly can be attributed to lot-to-lot variation and does not invalidate the original conclusion that the 1.50 mm and the 2.75 mm diameters represent the worst-case sizes for single layer and co-extruded balloons respectively, when tested for balloon outputs. *It appears that the sponsor did perform burst pressure and fatigue (not in stent) testing, for 5.0x12mm sizes in the engineering study, but the data does not clearly demonstrate that even at baseline, that the 2.75mm is worst case. Without testing with a statistically justified sample size from each lot, the sponsor cannot simply conclude that the variations seen between the worst case device sizes for aged and un-aged devices are due to lot-to-lot variability*

The sponsor provided a statistical comparison of aged and unaged devices (for sizes tested in both). For the 1.50 mm x 20 mm, the analysis shows a statistically significant increase. *This does not raise a*

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concern, as it indicates aging did not adversely affect RBP. For the 2.75 mm x 30 mm, the analysis shows a statistically significant decrease (17 vs 20atm RBP). The sponsor attributes this difference in rupture at baseline and aged to lot-to-lot variability. They state that this apparent significant decrease in aged samples does not raise a safety concern because all baseline and aged units meet the finished product specification of 206 psi (14 atm) minimum at 95% confidence / 99.9% reliability. *While this decrease is acceptable for RBP, since the RBP acceptance criteria is 14atm, the sponsor includes information up to 17atm in their labeling (which is within the allowable limit for labeling of 25% above RBP). Based on their engineering study, RBP of the 2.75mm balloon was calculated to be 242psi (16.5atm) post aging, and 255psi (17atm) from their Balloon Rupture test provided in the original submission. From the Balloon Compliance test submitted in the original submission, however, it does not appear that any of the ~17 samples tested failed at 255psi or lower. These data do not clearly demonstrate that with 99/95 confidence and reliability, the balloon would not fail at 17atm, which is the highest value listed in their compliance chart, in post-aged samples. The sponsor should modify their labeling accordingly (if needed).*

Deficiency:

3. Please address the following concerns regarding your Balloon Rupture test:
    a. Per our Guidance *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* the compliance chart may include pressures up to (but not exceeding) 25% above the RBP, if you provide data and statistics demonstrating that 99% of the balloons will not fail at the listed pressure with 95% confidence. It is unclear from the testing provided whether 99% of your catheters will not fail at 17 atm with 95% confidence, post aging, per the compliance chart in your IFU. Please clarify.
    b. If you determine that your data do not support the 17 atm failure pressure, please revise your compliance chart accordingly.

Question 14. Please address the following concerns regarding Balloon Rupture Within a Stent testing:

a. You did not perform this test using 1.50mm x 6mm size (smallest diameter x shortest length) device at baseline or post-aging. Please repeat testing using 1.50 mm x 6 mm size devices and provide a complete test report, or provide a scientific rationale for the omission of testing using this device size.

b. Please clarify what size stents were used for each balloon size tested.

Sponsor Response/ Reviewer Comments:
a. As noted in Q12 above, sponsor states that there are no 1.5mm diameter stents approved. The proposed indication associated with post-stent dilatation is applicable only to the 2.00 mm through 5.00 mm balloon diameters. There are 2.0mm diameter stents approved such as Abbott's Multi-Link 8 stent. *This response is* ***acceptable.***

(b)(4) and (b)(5) Inter-Agency

[redacted]

Question 15. Please address the following concerns regarding your Balloon Compliance testing:

a. The rationale behind the device sizes selected for post-aged testing was not clear. Please repeat Balloon Fatigue using aged samples of all "corner sizes" for both the MINI TREK and TREK catheters or provide a scientific justification for the sizes used for post-aged samples.

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b. It appears that there are different numbers of samples tested at different inflation pressures, in some cases with an increase in sample number with increasing pressure. Please clarify why there are a different number of samples at different inflation pressures.

c. Please provide a statistical comparison of balloon diameters at nominal and rated burst pressure between baseline and aged samples to demonstrate that aging has no significant effect on balloon compliance.

Sponsor Response/ Reviewer Comments:
a. Sponsor states that because there is no worst case size for compliance, the balloon compliance testing is collected concurrently with balloon rupture, the 1.50 x 20 mm and 2.75 x 30 mm size selections were based on the sizes used for balloon rupture testing. As addressed in Question 11 and 13, an engineering study identified the 1.50 mm and 2.75 mm sizes as worst case for balloon rupture testing. *It appears that the sponsor perform burst pressure and fatigue (not in stent) testing, for 5.0x12mm sizes in the engineering study, but the data does not clearly demonstrate that even at baseline, that the 2.75mm is worst case.*

b. Sponsor clarifies that during the compliance test, the balloon is submerged under water and inflated to the specified pressures, starting at 2 atm and increasing in 1 atm increments until rupture. A laser micrometer records the diameter measurement. Data are evaluated by comparing each compliance reading with the reading from the previous pressure, and if a balloon decreases in diameter with respect to the previous reading, it is considered to be erroneous and that data point is excluded from the analysis. Erroneous readings can be caused by environmental conditions such as air bubbles in the laser field. Balloon compliance is measured for each sample starting at 2 atm and is measured until the balloon ruptures; therefore, multiple measurements are taken on the same balloon. Data at each pressure are evaluated and erroneous data points are excluded. Although the number of samples tested remains the same, the sample size at each specific pressure may vary depending on the number of erroneous data points that are excluded.

c. The sponsor provided a statistical comparison for the 1.5mm and 2.75mm balloons at baseline and after 2yr aging. For the 1.50 mm balloon diameter, at both nominal pressure and RBP, the aged samples had smaller outer diameters than the baseline samples, by 0.02 and 0.03mm respectively. However, all baseline and aged units meet the finished product specification for outer diameter at nominal pressure. For the 2.75 mm balloon diameter, at both nominal pressure and RBP, the aged samples had larger outer diameters than the baseline samples, by0.03 and 0.05mm respectively. Again, all baseline and aged units meet the finished product specification for outer diameter at nominal pressure. *The differences between aged and baseline appears to be on the same order as the standard deviation, and although the differences are statistically significant, they are small and unlikely to have any clinical impact. This response is* ***acceptable****. Note that the sponsor attributes variation between aged and unaged to be due to lot-to-lot variation, but have not provided data to support this assertion.*

Question 16. *In your Distal Catheter Tensile (midlap seal) test, you did not perform a statistical analysis between aged and unaged samples. It appears that the TREK samples (5.0x15mm and 2.25x30mm) showed a substantial decrease in this property with aging, with a minimum strength of 1.5lbs in one of the samples. Please provide a statistical comparison of the aged and unaged samples and provide a scientific rationale for why you believe the decrease in Distal Catheter Tensile Strength with aging does not raise a safety concern.*

Sponsor Response/ Reviewer Comments: The sponsor performed a statistical comparison between aged and un-aged samples as requested. No statistically significant difference in Distal Catheter Tensile (midlap seal) was observed for the MINI TREK sizes. For the TREK sizes, a statistically significant difference in tensile values between aged and un-aged samples was observed, however, all data points exceed the 1.1 lb minimum product specification requirement. *From the original submission, the lowest tensile value for the TREK was 1.5lbs, with a mean of 2.1±0.34lbs. Even the lowest value is above the acceptance criteria of 1.1lb, so this decrease is* ***acceptable****. If this trend of decreasing tensile strength*

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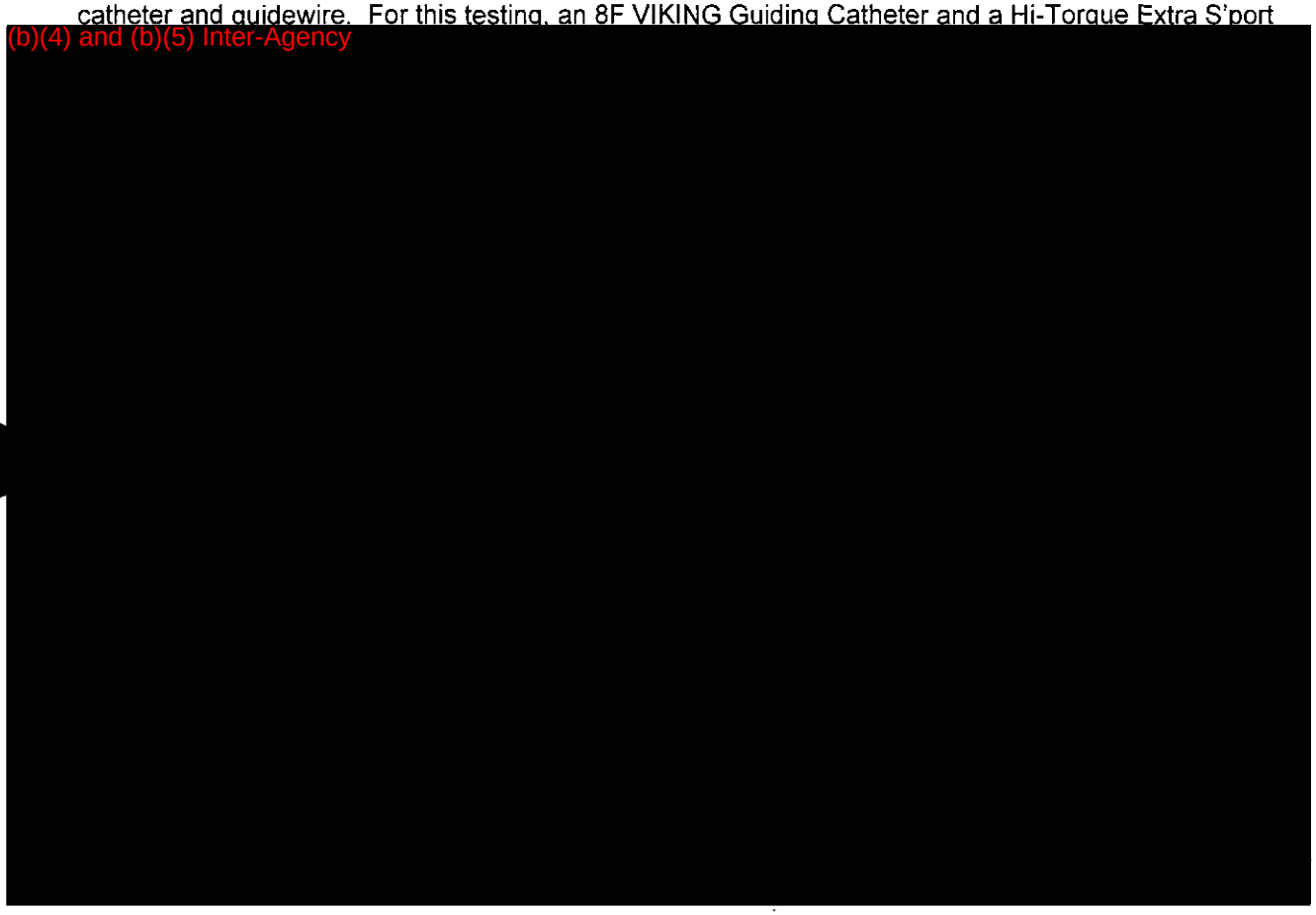
with aging continues, extension of shelf life would not be acceptable. Warning rolled into tensile strength deficiency above.

Question 17. Please repeat Catheter Coating Particulates Testing and address the following concerns in your repeated testing:

a. It appears you have flushed your tortuous tracking fixture after the guidewire and guide catheter were placed in the fixture, and discarded the effluent. Since patients would be exposed to the particles generated from these accessory devices necessary for the use of your device, please collect this effluent and report the total particulate count for this effluent.

Sponsor Response/ Reviewer Comments:
The sponsor performed testing to determine the particulate count generated from flushing the guiding catheter and guidewire. For this testing, an 8F VIKING Guiding Catheter and a Hi-Torque Extra S'port

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It is not clear how the guide wire and guide catheter were flushed; specifically whether the inside and outside of the guide catheter was flushed. However, the outside is rinsed per IFU before testing, so the contribution from the outside of the catheter is expected to be minimal. The amount of particulates generated in total appear to be very low, and does not raise a concern. This response is ***acceptable****.*

b. It was unclear from the photograph of your tracking fixture, whether the whole catheter is tracked through the fixture, or if only a distal segment is inserted into the fixture. Please make sure that the fixture is sufficiently long such that the whole patient contacting parts of the catheter can be tracked into the fixture, and particulates generated from this entire length are captured. In addition, you did not provide the critical dimensions of your test fixture (radius of curvature, diameter of track, etc.). Nevertheless, your fixture appears to be less tortuous than the coronary artery model in ASTM F 2394 – 04 Fig x2.4, and lacks the aortic arch portion. Please revise your tracking fixture to match the dimensions in ASTM F 2394 – 04 Fig x2.4 or equivalent.

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Sponsor Response/ Reviewer Comments: The whole patient contacting portion of the device enters the test system. The device is inserted from the rotating hemostasis valve (RHV). *It appears that with this test fixture, only the inside of the guide catheter would be assessed for particulates since there is no simulated vessel (i.e. the guide catheter is connected to the RHV on the proximal end and the tortuosity block on the other end. Specifically, the particulates from tracking the guide catheter would not be assessed in the current test setup. Nevertheless, this test setup would assess particulates generated from the guide catheter (and guidewire) interactions with the subject TREK and MINI TREK catheters, and particulates solely from the guide catheter should have been assessed in the review of those*

(b)(4) and (b)(5) Inter-Agency

[redacted]

The curvatures in the aortic arch (R=1.25") is less challenging compared to the aortic arch features in the ASTM figure x2.4 (R~0.5"). However, it appears the guide catheter overall is somewhat bent between the RHV and the tortuosity block, and the difference in curvature for the aortic arch segment is unlikely to significantly impact particulates generation due to the overall wide curvature of the aortic arch. It appears the guide catheter is bent into the aortic arch curve.

The sponsor compared the data from testing using the revised fixture with the aortic arch loop and the original fixture which did not have this portion. There were significantly fewer particulates (50µm bin) in the testing with the aortic arch

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[redacted]

The sponsor further justifies their test fixture by providing the dimensions of their tortuosity block (portion mimicking the coronary tortuosity), and stating that the curves are ≤15 mm bends, which has been accepted for Xience V (P070015/S016, Approved May 29, 2009) for their chronic particulates testing using overlapped stents in a bend. *Abbott's fixture has radius of curvatures varying from 10.01 to 19.99 mm (mean ~15mm) while the ASTM fixture has radius of curvatures varying from 3.18 to 6.35 mm (mean ~5mm). We have accepted this tracking fixture in G090068/S7 and S12 for the Xience Prime Coronary DES. It appears the fixture used for the 5.00mm balloon was not used for Xience Prime (likely due to the available device sizes). While it is not likely that a 5.00mm balloon would be used in the smaller distal coronaries, such as those modeled in the ASTM fig x2.4 fixture, Abbott did not provide a clinical rationale for the less stringent fixture they used for the 5.0mm balloon.*

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[redacted]

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[redacted]

c. You state that "particulate test results are independent of balloon size due to commonality of materials and construction" as a justification for not testing all 4 corner sizes. We do not agree with this statement since the inflation/deflation of the balloon of different sizes will cause different stress/strains in the coating, and it is unclear which sizes may be worst case in this regard. Since your other catheters using the same coating have different balloon materials for the balloon size ranges covered in the TREK and MINI TREK, we cannot conclude that the particulation behavior will be the same. Please include 4 corner sizes for your repeated testing. For aged sample testing, please include the device size that was worst case for each chassis size.

Sponsor Response/ Reviewer Comments: Sponsor states that for baseline testing, the 2.0 x 6mm and the 5.0 x 15mm were tested as representative of the smallest and largest sizes (diameter and length) in the balloon matrix that are indicated for the post-stent dilatation indication. The outer layer material of the MINI TREK and TREK balloons is identical and therefore the balloon type (single vs. double layer) is not a factor in the particulate size selection rationale. In addition, the 4.0 x 30mm was tested as a worst case because it has the largest balloon surface area that contacts the stents. The 4.0 x 30mm was tested post aging because this was the worst case at baseline. *Testing using the 2.0mm instead of 1.5mm diameter as the worst case clinical condition of inflation in a stent, which will not occur using the smallest 1.5mm diameter size, is acceptable. It is also acceptable not to include the 'inside corner' sizes between the Mini TREK and TREK because the outer balloon material is the same, and therefore the corners of the entire size matrix is representative of all of the devices (both TREK and Mini TREK), in this case. However, the smallest diameter x longest (2.0x30mm) was not tested so we cannot determine whether the 4.0x30mm had higher particulates counts because of the diameter or length. Specifically, the average particulates from the 4.0x30mm balloon had less than 5x that of the 2.0x6mm balloon, extrapolating based on balloon length, which suggests that the 2.0x30mm may have higher particulate counts than the 4.0x30mm balloon. If the 2.0x30mm is worse at baseline, the sponsor should also use this size for aged samples. Also, since the MINI TREK 1.2mm balloon is currently under IDE G100141, and testing for the 1.2mm size will be needed once the IDE is complete and a 510(k) is submitted for this device, the sponsor can be offered to provide testing on the 1.2mm sizes to fulfill the lower 2 corners, in lieu of testing the 2.0x30mm.*

d. We recommend that the total number of particulates be reported in each of three size ranges: ≥10µm, ≥25µm, and at the largest size for which validation yields ≥75% recovery. At a minimum, the largest size should be ≥50µm. Your testing did not include the largest particle size bin.

Sponsor Response/ Reviewer Comments: Sponsor has provided the requested data using the same limited sizes used for their initial testing. The validation data demonstrates a minimum of 75% recovery for both the 50 µm and 70 µm bin sizes.

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[redacted]

e. Please perform a validation test for your test fixture (spike and recovery test using particles of know size and quantity, for each size bin outlined in part d above), and provide a complete test report for this validation. FDA is amenable to reviewing your test protocol informally prior to test initiation.

Sponsor Response/ Reviewer Comments: The sponsor performed spike and recovery testing using their revised test fixture including the aortic arch (Appendix 17-1).

Acceptance criteria:

- 90 ≤ percent recovery; ≤ 110 for 10 and 25 micron spheres
- 75 ≤ percent recovery; ≤ 110 for 50 and 70 micron spheres

Duke Scientific standard spheres were injected into the proximal end of the guide catheter. Each of the 3 test fixtures were assessed and a 15mL aliquot of effluent was measured using 2 different light obscuration particle counters. It appears n=4 samples were used for 10 and 25µm bins, and n=2 for the 50 and 75µm particle bins. Effluent samples were also re-tested after a 'cleanliness check' of the particle counter and 'additional degas procedure'. All of the initial effluent test samples passed, while one measure each of the 25, 50 and 75µm bin samples failed in the retest. This indicates that the extra steps taken (cleanliness check and degas) may have introduced additional particles or counting error. *Overall, the validation results were acceptable and met the acceptance criteria.*

Note: The TLT2065633-40 fixture (used for embolic fatigue per spike and recovery test protocol) and TLT2065633-25 (used for the 2.0mm balloon) uses the same tortuosity block but a different size tubing in the block (per 11/24/10 email). It appears the tubing used for the spike and recovery test was larger than that used in the 2.0mm balloon testing. Since the validation for the 4.0mm balloon fixture with similar tortuosity and a further larger tubing showed similar results, it is reasonable to extrapolate that the difference in tubing size used for the validation and actual 2.0mm particulates testing would not significantly impact the validation outcomes. Nevertheless, the sponsor should be advised to use the same exact test setup for validation and testing, and to clearly note if there are differences (as this difference was obscure in the test reports).

f. Please clarify what accessory devices (guide catheter and guidewire) and stents were used in your test.

Sponsor Response/ Reviewer Comments:
The following accessory devices were used during Catheter Coating Particulate Testing:

- Hi-Torque Extra S'port Guidewire, K021285, Cleared 5/2/2002
- VIKING Guiding Catheter, K972484, Cleared 9/26/1997
- MULTI-LINK MINI VISION Coronary Stent, P020047/S003, Approved 9/10/2004
- MULTI-LINK VISION Coronary Stent, P020047, Approved 7/16/2003

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- MULTI-LINK ULTRA Coronary Stent, P970020/S021, Approved 9/8/2000

The sponsor should clarify what sizes of these accessories and stents were used with each device size tested. This would guide the labeling.

g. In your IFU p.6 you state "After the deflated balloon dilation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile, heparinized normal saline and stored. Prior to reinsertion, the balloon should be submerged in sterile, heparinized normal saline to reactivate the coating." However, this process of wiping with gauze and reinserting was not performed for your particulates test. Please include these steps in your new particulates testing.

Sponsor Response/ Reviewer Comments: The sponsor states that wiping with gauze to remove dried blood particles is standard cath lab practice, but how this is performed is outside the control of the sponsor. They state that particulates testing is to assess and reduce particulates from manufacturing. *Given that we do not request other manufacturers to assess particulates post wiping with gauze, or other manipulations of the device that may occur in the cath lab, this response is* ***acceptable****.*

h. You have performed 3 inflations in the overlapped stents in your fixture. The maximum number of inflations was not specified in your instructions for use (IFU). Please perform the same number of maximum inflations in your particulates test, to the maximum labeled diameter, as you intend to state in your IFU, and update your IFU accordingly.

Sponsor Response/ Reviewer Comments: Abbott Vascular has revised the IFU to include the maximum number of inflations (10 within a stent, 20 without a stent; Attachment 19). For particulates testing, the 3 inflations were performed to 17atm, which is the max labeled, and above the RBP of 14atm, to simulate a worst case for particulates testing. *Since the balloon fatigue testing within and without a stent to RBP passed, 10 and 20 inflations respectively, this labeling is appropriate. See 8/19/10 email to sponsor. This response is* ***acceptable****.*

i. Please perform a visual assessment of your catheter coating integrity after particulates testing. We recommend that you appropriately quantify characteristics such as continuity and voids in the coating, using a sufficient magnification to visualize the defects. Please also include representative images (including worst-case) in your test report.

Sponsor Response/ Reviewer Comments: The sponsor used a red dye to visualize the coating on the 4.00 x 30 mm size devices, deemed to be the worst case. The dyed catheters were tracked through the fixture used for particulates assessment. The following locations on the coated region were examined under 30x magnification:

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There were no visible defects or gaps in the coating. *This response is* ***acceptable****. However, if the 2.0x30mm devices are identified to be worst case for particulates, this testing should be repeated on those devices as well.*

Deficiency:

4. Please address the following concerns regarding your Particulates Testing:

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a. You state that for baseline testing, the 2.0 x 6mm and the 5.0 x 15mm devices were tested as representative of the smallest and largest sizes (diameter and length) in the balloon matrix that are indicated for the post-stent dilatation indication, and the 4.0 x 30mm devices were tested as a worst case because it has the largest balloon surface area that contacts the stents. You also justify testing only the 4.0 x 30mm devices post aging because this size had the highest particulation at baseline. Since you did not test the 2.0 x 30mm size, which is one of the 4 corners of your device size matrix, at baseline, we cannot determine conclusively that the 4.0 x 30mm is the worst case size. In particular, the 2.0 x 6mm devices had greater than 1/5th the mean particulates count of the 4.0 x 30mm devices. This suggests that the 4.0 x 30mm devices may have appeared to be worst case due to the longer length of the balloon, but in fact, the 2.0 x 30mm devices may be the true worst case devices in terms of particulates generation. Please repeat testing using the 2.0 x 30mm devices at baseline and provide an updated test report.
b. If you determine from the 2.0 x 30mm devices tested at baseline that this size is the true worst case in terms of particulates generation, please also perform particulates testing using 2.0 x 30mm devices aged to your proposed shelf life. Please make sure to incorporate recommendations made in deficiency #17, such as including a ≥50µm particle bin size, accounting for particles from flushing the accessory devices after placement, etc. In addition, if the 2.0 x 30mm devices are determined to be the worst case, please also perform a visual assessment of the coating.
c. Please make sure to include both RX and OTW devices for this additional testing, or provide a scientific justification for only using one device configuration.
d. In your particulates validation testing, it appears you have used a slightly different 2.0mm device size test fixture than what was actually used to assess particulates generation (per November 24, 2010 email). Specifically, the tubing diameter used within the tortuosity base plate was slightly different. While this is acceptable since validation results for the 4.0mm device fixture with similar tortuosity to the 2.0mm fixture and a further larger tubing size showed similar results, please acknowledge that for future testing you will use the same exact test setup and methods in your validation testing as in your actual device testing. Please also acknowledge that if you have differences in your validation test setup or protocol (flushing etc.) that you will clearly identify and justify these differences in future submissions.

Question 18. It appears that you have used a room temperature value of 20°C (68°F) to calculate your accelerated aging factor, which is less conservative than using a more typical value for room temperature (23-25°C). FDA believes that the devices will be exposed to ambient temperatures above 20°C during transport and storage. If a room temperature value of 25°C was used, 65 days of aging at 55°C (functional testing) and 46 days of aging at 60°C (packaging) would be equivalent to 520 days, rather than 2 years as you have calculated. Please either reduce your shelf life claim in the future marketing application to match the shelf life duration supported with testing using a more conservative value for room temperature, perform additional shelf life testing to support your proposed 6 month shelf life, or provide a scientific justification for why you believe a room temperature value of 20°C is appropriate.

Sponsor Response/ Reviewer Comments: The sponsor recalculated their accelerated aging based on the Arrhenius equation in ASTM F1980 (Af= aging factor).

$$A_f = 2^{\frac{T_e - T_a}{10}}$$

T_e = elevated temperature (°C)

T_a = ambient temperature (°C)

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calculations. This response is ***acceptable****.*

Question 19. Please address the following concerns regarding your Instructions for Use (IFU):

a. Please include the maximum number of inflation cycles, both in a stent (post dilatation) and not in a stent

b. The Rx only symbol was not included in the graphical symbols glossary at the end of your IFU. Please add the symbol to your glossary. Please also add the statement "Caution: Federal law restricts this device to sale by or on the order of a physician."

c. Please provide a red-lined copy of your IFU with the above changes incorporated.

Sponsor Response/ Reviewer Comments:

a. The sponsor has added the max number of inflation cycles as requested. *This response is* ***acceptable****.*

b. Abbott Vascular has chosen to use the "Rx only" symbol as an alternative to the prescription labeling requirements, based on the Guidance for Industry – Alternative to Certain Prescription Device Labeling Requirements, January 21, 2000 which states:

> "CDRH would like to minimize the burden on manufacturers, repackers, relabelers and distributors that face a variety of labeling requirements and changes. Therefore, CDRH, in its enforcement discretion, does not intend to object to the use of the statement "Rx only" as an alternative to the prescription device labeling statement "Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)."

Additionally, this guidance states that, "additional prescription statements are not required if the 'Rx only' symbol is present." *This response is* ***acceptable****.*

c. The sponsor provided a red-lined copy of the revised IFU in Appendix A19-1. *This response is* ***acceptable****.*

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Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:
This is a device change to an earlier version of the sponsor's own PTCA catheter.

4. Explain how new characteristics could or could not affect safety or effectiveness:
The new characteristics are similar to other PTCA catheters (materials, sizes, design) and the concerns identified are not new.

5. Explain how descriptive characteristics are not precise enough:
Sizes used for post-aged bench testing and particulates was not acceptable (missing a device size) or insufficiently justified. Some color additives questions also remain, to be answered by the MAF/DMF holders for the colorants.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:
Sizes used for post-aged bench testing and particulates was not acceptable (missing a device size) or insufficiently justified. Some color additives questions also remain, to be answered by the MAF/DMF holders for the colorants.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

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XV. Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (http://www.fda.gov/cdrh/modact/guidance/1195.html) and "A Suggested Approach to Resolving Least Burdensome Issues" (http://www.fda.gov/cdrh/modact/leastburdensome.html).

See deficiencies above in blue text, and letter for final wording.

XVI. Contact History

- 11/24/10 email—sponsor provided requested additional information on testing to determine sizes to be tested post aging, clarification on adhesives used, confirmation of applicability of correspondences regarding biocompatibility sent for G100141, clarification on particulates test fixture, and confirmation of proposed shelf life duration.
- 11/9/10 email—sponsor provided administrative documents needed due to the conversion from a PMA to a 510(k).
- 9/29/10 email—sponsor provided clarifications regarding test samples used for biocompatibility testing (referenced G100141 but confirmed to be applicable to the subject submission 11/24/10)
- 9/2/10 and 9/13/10—telecon regarding colorants and follow up email with minutes
- 8/19/10 email—feedback regarding number of inflations for particulates testing
- 8/16/10 telephone call—provided feedback regarding:

(b)(4) and (b)(5) Inter-Agency [redacted]

XVII. Recommendation

Regulation Number: 21 CFR 870.5100]
Regulation Name: Percutaneous Transluminal Coronary Angioplasty Catheter
Regulatory Class: Class II,
Product Code: LOX

12/1/10

Erica Takai, Ph.D.
Scientific Reviewer (Biomedical Engineer)
Interventional Cardiology Devices Branch
Division of Cardiovascular Devices
ODE / CDRH / FDA

12/2/10

Ashley Boam, MSBE
Branch Chief
Interventional Cardiology Devices Branch
Division of Cardiovascular Devices
ODE / CDRH / FDA

219

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) and (b)(5) Inter-Agency

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(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

(b)(4) and (b)(5) Inter-Agency

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

1.0 Purpose

This study will determine the worst case size to use as justification for the sizes selected for aging, both real time and accelerated.

2.0 Background

According to the four corner paradigm outlined in the Draft FDA Guidance, balloon rupture testing (both unconstrained and in-stent) would require the longest length of every diameter and the shortest length of both the smallest and largest diameter. The 1.25 mm size will not be marketed in the US; therefore, the 1.5mm size becomes a corner size for the US filing.

(b) (4)



The draft guidance states that if testing is not conducted according to the four corners paradigm, a scientific rationale to support the sizes that were tested, and that an analysis can be performed to identify the size or sizes that represent the worst case. Additionally, DOP681 Revision H allows for data to be grouped logically and that worst case sizes can represent the range of sizes with appropriate justification.

Using a worst case size, a minimum of one for each balloon process/design configuration, would significantly reduce the sizes required for aging.

3.0 Executive Summary

The group, per balloon design/process configuration, with the lowest calculated RBP will be the size selected as the worst case for aging. Based on the data and calculations, the 1.5 x 20mm is the worst case balloon size for the MINI TREK RX CDC (single layer material and one stage balloon blow process) and the 2.75 x 30mm is the worst case balloon size for the TREK RX CDC (dual layer balloon and two stage balloon blow process).

4.0 Deviations

4.1 According to the test matrix in the protocol, a minimum of 45 units were to be tested for balloon rupture per diameter. The 1.25 mm and 3.00 mm sizes only had 44 units for balloon rupture. On the 1.25 mm size, one unit ruptured at 325 psi in the proximal seal (TR100298210) and was an outlier on the low side and therefore removed from the data set. The proximal seal process has since been optimized which may reduce to occurrence of low ruptures (see Section 9.0). On the 3.00 mm size, one unit ruptured at 436 psi (TR100299391) which was an outlier on the high side and therefore removed from the data set. Outliers are shown in the distribution plots (see Attachment C). This is acceptable as a minimum of 30 units is required per DOP205 in order to demonstrate confidence and reliability for variable data with an S-4 severity.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

4.2 According to the test matrix in the protocol, a minimum of 45 units were to be tested for balloon fatigue per diameter. The 1.25 mm and 3.75 mm did not meet the minimum requirement. For the 1.25 mm size, 42 units were tested for balloon fatigue. This was due to a shortage of units built for the 1.25 x 20mm size. For the 3.75 mm size, 44 units were tested for balloon fatigue. This was due to a visual failure (gel on the distal shaft) on one unit in the 3.75 x 30mm group (TR100306970). This is acceptable as the confidence and reliability requirement was still met for these sizes.

4.3 According to the test matrix in the protocol, a minimum of 15 units were to be tested for balloon working length on the 1.25 x 20 mm and a minimum of 10 units were to be tested on the 3.25 x 6 mm size. However, there were no units available to test for working length on the 1.25 x 20 mm size or 3.25 x 6 mm size. This was due to a shortage of units built on those sizes. This is acceptable as working was tested on the 1.50 x 20 mm size and on all other 6 mm length balloons. In addition, the results met the acceptance criteria with 95/95 confidence/reliability.

4.4 The 1.5 mm size and 3.00 – 5.00 mm sizes did not meet the minimum requirement of 45 units per diameter for balloon compliance due to issues with test equipment. During balloon compliance testing, it was noted that units had dips during compliance or low readings throughout the test pressures. These types of failures are test method related. Compliance data by nature should increase with each pressure increment. If a sample decreases in compliance (with the previous reading) with an increase in pressure then it is considered erroneous data. Environmental factors within the test method cause erroneous data such as balloon offset in fixture, lint/particles in water, movement of laser/fixture and bubbles on the balloon. All data is reviewed by engineering and the test lab for erroneous data.

4.5 Certain sizes were originally built on engineering LHRs (2.00 – 2.75 mm sizes) as the green tagged balloon molds were not available at the time of building. Once the green tagged balloon molds became available, additional units were built on non-human use LHRs. There were only minor differences between the engineering use balloon molds and the non-human use balloon molds. Changes included document revision changes (number to letter rev) or external mold changes to reduce mold wall thickness to decrease processing times. Therefore, data from both the engineering LHRs and non-human use LHRs were combined. This is shown with the increased sample size for balloon rupture and compliance testing. This is acceptable as the minimum requirement for each output was satisfied.

4.6 The original data set generated for the 3.25mm size for balloon rupture and compliance was not optimal (TR100288910, TR100288911). The compliance was higher than anticipated. This balloon mold was modified to reduce the working length ID of the mold from 0.1525" to 0.1445". Units were rebuilt using this new mold. Only the rebuilt units were used in the data analysis. This is acceptable as the original units did not meet the requirements and will not be used in the final configuration.

4.7 The original data set generated for the 3.75mm size for balloon rupture, compliance and fatigue was not optimal (TR100288913, TR100288930). The compliance was higher than anticipated and the balloon rupture and fatigue did not meet the acceptance criteria. This balloon mold was modified to reduce the working length ID of the mold from 0.1525" to 0.1445". Units were rebuilt using this new mold. Only the rebuilt units were used in the data analysis. This is acceptable as the original units did not meet the requirements and will not be used in the final configuration.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

4.8 The 1.25mm and 3.25 mm sizes failed to meet the acceptance criteria for balloon compliance at nominal pressure. The acceptance criteria stated nominal outer diameter was to be achieved within 7 – 9 atm. Nominal OD was achieved on the both the 1.25mm and 3.25mm sizes at 11 atm (165 psi). Marketing made a decision to increase the nominal on the 1.25 mm size from 8 atm to 11 atm based on the compliance data. For the 3.25mm size, a new mold has been ordered with a working length ID of 0.1285". This change was made to meet the compliance requirement of 8atm. The new mold working length ID is between the two mold working length IDs that were tested in this study (0.1285" is between 0.131" and 0.126"). Both groups tested in this study passed C/R for rupture as seen in Attachment B. Thus, the new mold, with a working length ID of 0.1285", is expected to meet C/R for rupture as well.

5.0 Test Samples

See attachment B for a list of the part numbers and lot numbers used for this study. All units were EtO sterilized using cycle 102/103.

6.0 Materials and Equipment

Materials and equipment that require documentation were recorded in the build documentation XLHRBM1012268.

7.0 Acceptance Criteria

(b) (4)

[redacted]

* The confidence and reliability requirements for these attributes are driven by external standards and are not determined by the severity level.
** Confidence, reliability, and severity do not apply to these attributes because they are design requirements per DDD2061559 and are not incorporated into risk assessment activities.

Each fatigue test sample was tested to 40 cycles and the data from 20 to 40 cycles is for engineering purposes only and not considered for the fatigue acceptance criterion.

The group, per balloon design/process configuration, with the lowest calculated RBP will be the size selected as the worst case for aging.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Testing

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

(b)(4) Testing

[redacted]

RE testing of the 1.5mm aging lots, two units failed to meet the distal catheter tensile minimum requirement of 1.1 lb (NCMR65598). Further investigation showed the tip to IM and proximal seal processes required further optimization as the design in composite was weaker than the individual bonds. The soft tip material was changed from 70D to 72D and the proximal seal process was optimized in order to address this concern. The optimized distal seal process and proximal seal process do not affect the outputs of this study. Reference memos in Attachment E.

10.0 Conclusion

The results of this study were used to select the aging sizes to be tested for balloon rupture and fatigue. As discussed in the balloon rupture data analysis, many of the balloon diameters are considered equivalent and any of the sizes within those groups can be tested for aging. For aging, the 1.5mm and 2.75mm sizes will be built for balloon rupture and fatigue; however, if during filing testing another size is shown to have a lower RBP as long as that size is one of the representative sizes (listed in Section 8.0.1) , aging will not have to be rebuilt, as the sizes built for aging will still be representative of the worst case size for balloon rupture and fatigue.

11.0 References

The references shown below reflect the revisions at time of report creation.

DOP205, rev AA	Process Validation – OQ and PQ
DOP681, rev H	Filing and Aging Testing
PS1012268, rev E	TREK and MINI TREK Product Specification
STM2010257, rev BY	HBLT/Laser Mic Auto-Compliance/Rupture
STM2048456, rev M	Balloon Inflation Fatigue, Incremental
STM2037574, rev AH	Balloon Working Length
XLHRBM1012268, rev 9	TREK RX and MINI TREK RX CDC

12.0 Attachments

Attachment A:	Xcalibur RX-Aging Worst Case Size Determination Protocol
Attachment B:	Raw Data
Attachment C:	Normality and Outlier Analysis
Attachment D:	Equivalency Analysis
Attachment E:	Memos Addressing Process Changes due to Tensile Failures
Attachment F:	Formulas/Calculations
Attachment G:	Part Numbers and Lot Numbers
Attachment H:	Failure to Prep Investigation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Attachment A: Xcalibur RX Aging Worst Case Size Determination Protocol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

XRX253

Xcalibur Balloon Blow
Aging Worst Case Size Determination

Protocol

Author: Kristen Nolan
July 17, 2009

(b) (6)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Protocol

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(b)(4) Protocol

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Attachment B: Raw Data

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Attachment C: Normality and Outlier Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Analysis

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Attachment D: Equivalency Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) and (b)(5) Inter-Agency

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. SUBMITTER'S NAME	Abbott Vascular Inc.
2. SUBMITTER'S ADDRESS	26531 Ynez Road, Temecula, CA 92591
3. TELEPHONE	(951) 914-3243
4. FAX	(951) 914-0339
5. CONTACT PERSON	Suzanne Redman
6. DATE PREPARED	November 9, 2010
7. DEVICE TRADE NAME	TREK™ RX Coronary Dilatation Catheter MINI TREK™ RX Coronary Dilatation Catheter TREK™ OTW Coronary Dilatation Catheter MINI TREK™ OTW Coronary Dilatation Catheter
8. DEVICE COMMON NAME	• Coronary Dilatation Catheter • Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
9. DEVICE CLASSIFICATION NAME	PTCA Catheter (LOX)
10. PREDICATE DEVICE NAME	VOYAGER® RX Coronary Dilatation Catheter VOYAGER® NC Coronary Dilatation Catheter VOYAGER® OTW Coronary Dilatation Catheter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

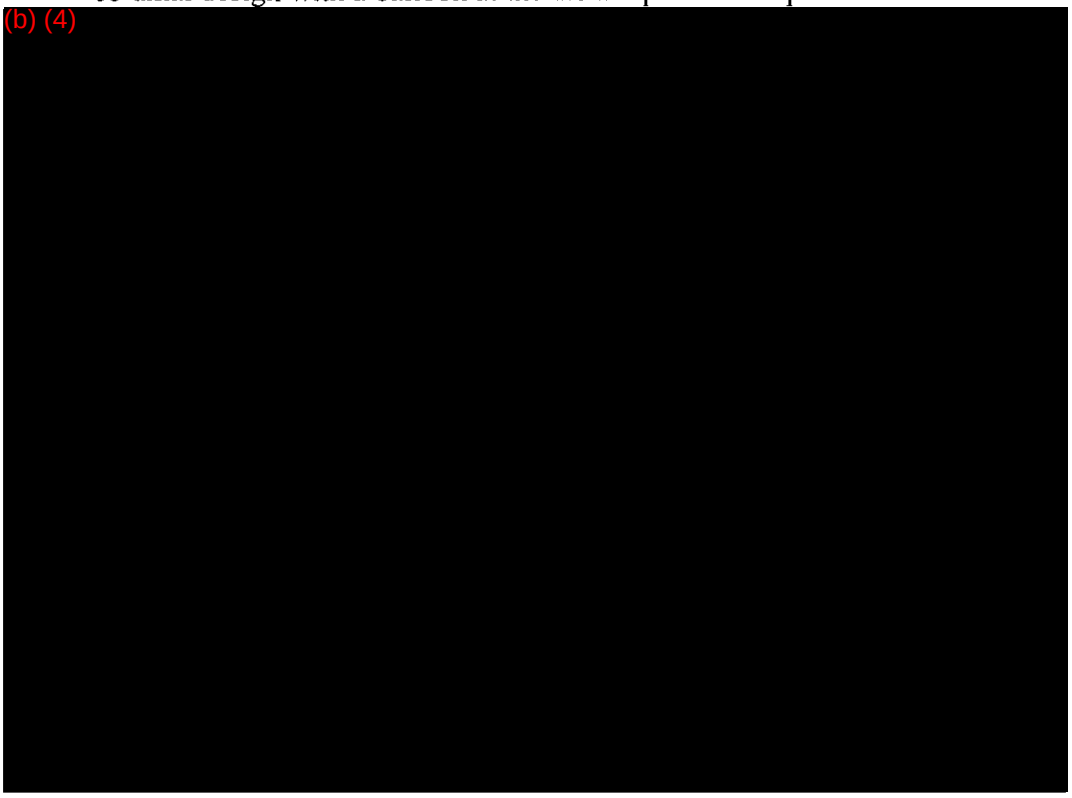
Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

11. DEVICE DESCRIPTION

11.1 TREK RX and MINI TREK RX Coronary Dilatation Catheter

The TREK RX and MINI TREK RX Coronary Dilatation Catheters are a rapid exchange co-axial design with a balloon at the distal tip. **Table 1** provides a matrix of the balloon

(b) (4)



The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. The coaxial shaft consists of a tubular inner and outer member. The inner member permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. The proximal shaft consists of a hypotube with a hub on the proximal end, a tapered distal section ending distal to the guide wire notch junction, along with brachial and femoral markers.

11.2 TREK OTW and MINI TREK OTW Coronary Dilatation Catheter

The TREK OTW and MINI TREK OTW Coronary Dilatation Catheters are an over-the-wire co-axial design with a balloon at the distal tip. **Table 2** provides a matrix of the balloon diameters and lengths available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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The balloon segment expands to a known diameter and length at a specific inflation pressure and has radiopaque marker(s) under the balloon to aid in positioning the balloon in a stenosis. The coaxial shaft consists of a tubular inner and outer member. The inner lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The outer lumen provides for inflation and deflation of the balloon with contrast fluid. Along the proximal portion of the shaft are brachial and femoral markers to aid in gauging the catheter's position relative to the guiding catheter tip when introducing the catheter through the guiding catheter. An adaption arm is located at the proximal end to provide access to the inflation lumen and guide wire lumen and allows connection with an inflation device.

12. INDICATIONS FOR USE

The TREK™ RX, MINI TREK™ RX, TREK™ OTW, and MINI TREK™ OTW are indicated for:

a) balloon dilatation of the stentotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;

b) balloon dilatation of a coronary artery occlusion of the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;

c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

13. TECHNOLOGICAL CHARACTERISTICS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

14. PERFORMANCE DATA

The TREK RX, MINI TREK RX, TREK OTW and MINI TREK OTW Coronary Dilatation Catheters were subjected to the following *in vitro* bench tests according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September

(b)(4) Analysis

[redacted]

Biocompatibility testing included cyctotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, and complement activation.

These in vitro bench and biocompatibility tests demonstrated that the TREK RX, MINI TREK RX, TREK OTW and MINI TREK OTW Coronary Dilatation Catheters met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and therefore, these devices may be considered substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

TRUTHFUL AND ACCURATE STATEMENTS

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Principal Regulatory Affairs Associate of Abbott Vascular, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Suzanne Redman
Principal Regulatory Affairs Associate

11/9/2010
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

INDICATIONS FOR USE

510(k) Number (if known): K103110

Device Names: TREK™ RX Coronary Dilatation Catheter
MINI TREK™ RX Coronary Dilatation Catheter
TREK™ OTW Coronary Dilatation Catheter
MINI TREK™ OTW Coronary Dilatation Catheter

Indications for Use: The TREK™ RX, MINI TREK™ RX, TREK™ OTW, and MINI TREK™ OTW Coronary Dilatation Catheters are indicated for: a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perforusion;
b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segement elevation myocardial infarction;
c) balloon dilatation of a stent after implantation (balloon models 2.0 mm – 5.0 mm only).

Prescription Use____X____ (Per 21 CFR 801.109) OR Over-The-Counter_____ (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of __

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Abbott Vascular

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
11/9/2010

3. ADDRESS *(Number, Street, State, and ZIP Code)*
26531 Ynez Road
Temecula, CA 92591

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 951-914-3243
(Fax) 951-914-0339

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

TREK RX Coronary Dilatation Catheter

MINI TREK RX Coronary Dilatation Catheter

TREK OTW Coronary Dilatation Catheter

MINI TREK OTW Coronary Dilatation Catheter

Coronary Dilatation Catheter

Percutaneous Transluminal Coronary Angioplasty Catheter (PTCA)

See ATTACHMENT 1 for Model Numbers

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
K103110

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense. U.S. Code title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Suzanne Redman
(Title) Principal Regulatory Affairs Associate

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
26531 Ynez Road
Temecula, CA 92591

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 951-914-3243
(Fax) 951-914-0339

15. DATE OF CERTIFICATION
11/9/2010

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 DF

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the *common* or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. *Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.*
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (11/08) (BACK)

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Records processed under FOIA Request #2014-6010, released by CDRH on 02-01-2016.

Abbott Vascular Inc.
Regulatory Affairs
26531 Ynez Road
Temecula, CA 92591

K103110/S1

FDA CDRH DMC
DEC 7 2010
Received

December 6, 2010

FDA CDRH DMC
07 2010
Received

Document Mail Center (W066-G609)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Amendment to 510(k) K103110 for the TREK™ RX, MINI TREK™ RX, TREK™ OTW and MINI TREK™ OTW Coronary Dilatation Catheters

To Whom It May Concern:

Please find enclosed an amendment to 510(k) K103110 for the TREK™ RX, MINI TREK™ RX, TREK™ OTW, and MINI TREK™ OTW Coronary Dilatation Catheters. The purpose of this amendment is to respond to the deficiencies received in the letter from FDA dated December 2, 2010.

Responses to each deficiency are included as individual attachments with supporting appendices where applicable.

Two paper copies of this amendment to 510(k) K103110 have been submitted to the Document Mail Center. An electronic copy, per FDA instructions, has been provided in lieu of a third paper copy. The electronic copy is an exact duplicate of the paper copy. The data and other information contained in this 510(k) are confidential, and the protection afforded to such confidential information by 18 USC 1905, 21 USC 331 (J), 5 USC 552, and other applicable laws is hereby claimed.

If you have any questions or require any additional information, please contact me at (951) 914-3243 or Sean Mullin, Regulatory Affairs Manager, at (941) 491-3031. I may also be reached by fax at (951) 914-0339 or by e-mail at suzanne.redman@av.abbott.com.

Sincerely,

K30

Suzanne Redman
Principal Regulatory Affairs Associate

Abbott
A Promise for Life

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

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Abbott Vascular Inc.
Regulatory Affairs
26531 Ynez Road
Temecula, CA 92591

December 6, 2010

Document Mail Center (W066-G609)
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Food and Drug Administration
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Sincerely,

Suzanne Redman
Principal Regulatory Affairs Associate

Abbott
A Promise for Life

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(b) (5)

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Records processed under FOIA Request #2014-8110; Released by CDRH on 02-01-2016.

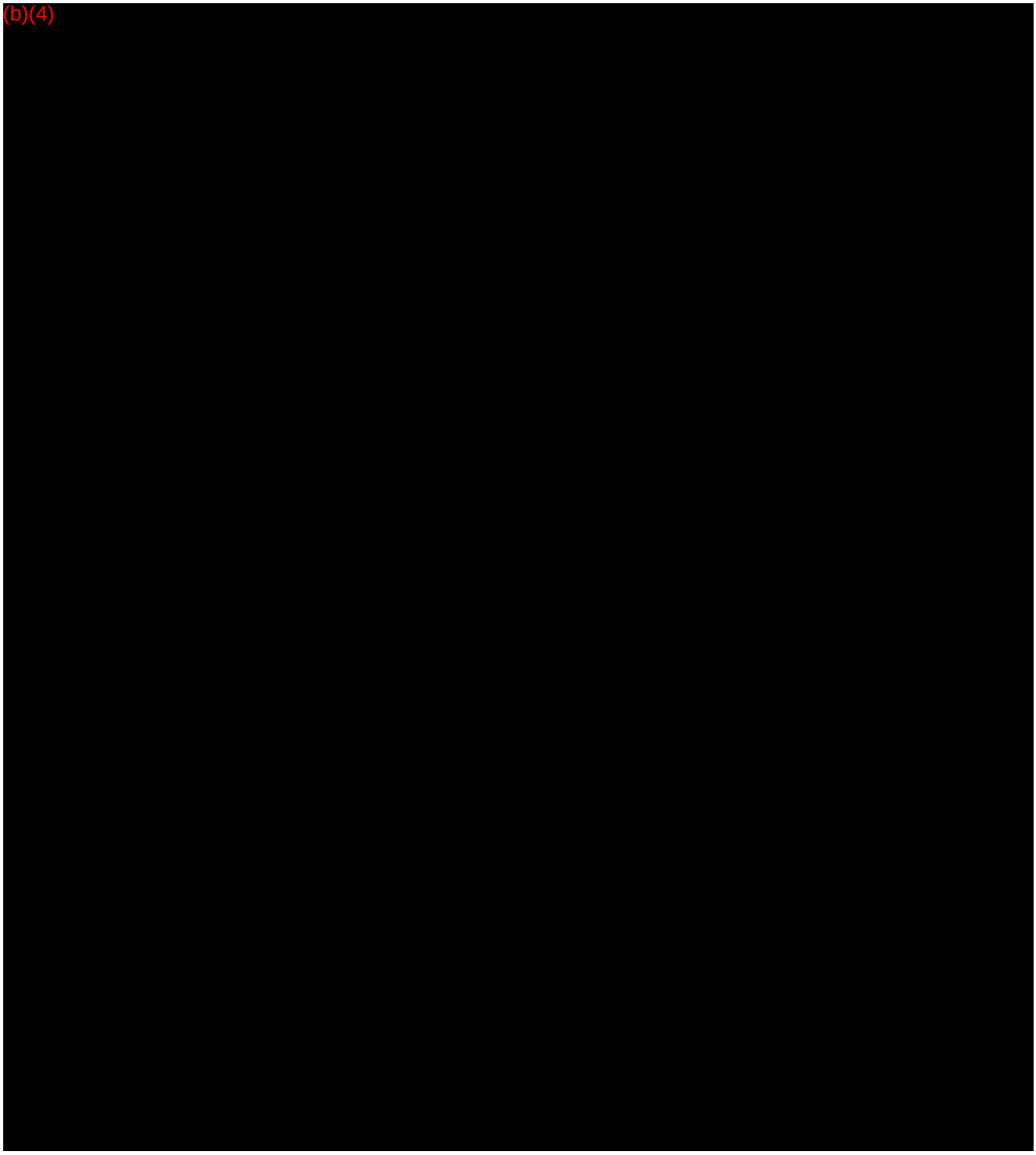
(b)(4)



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(b)(4)



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(b)(4)

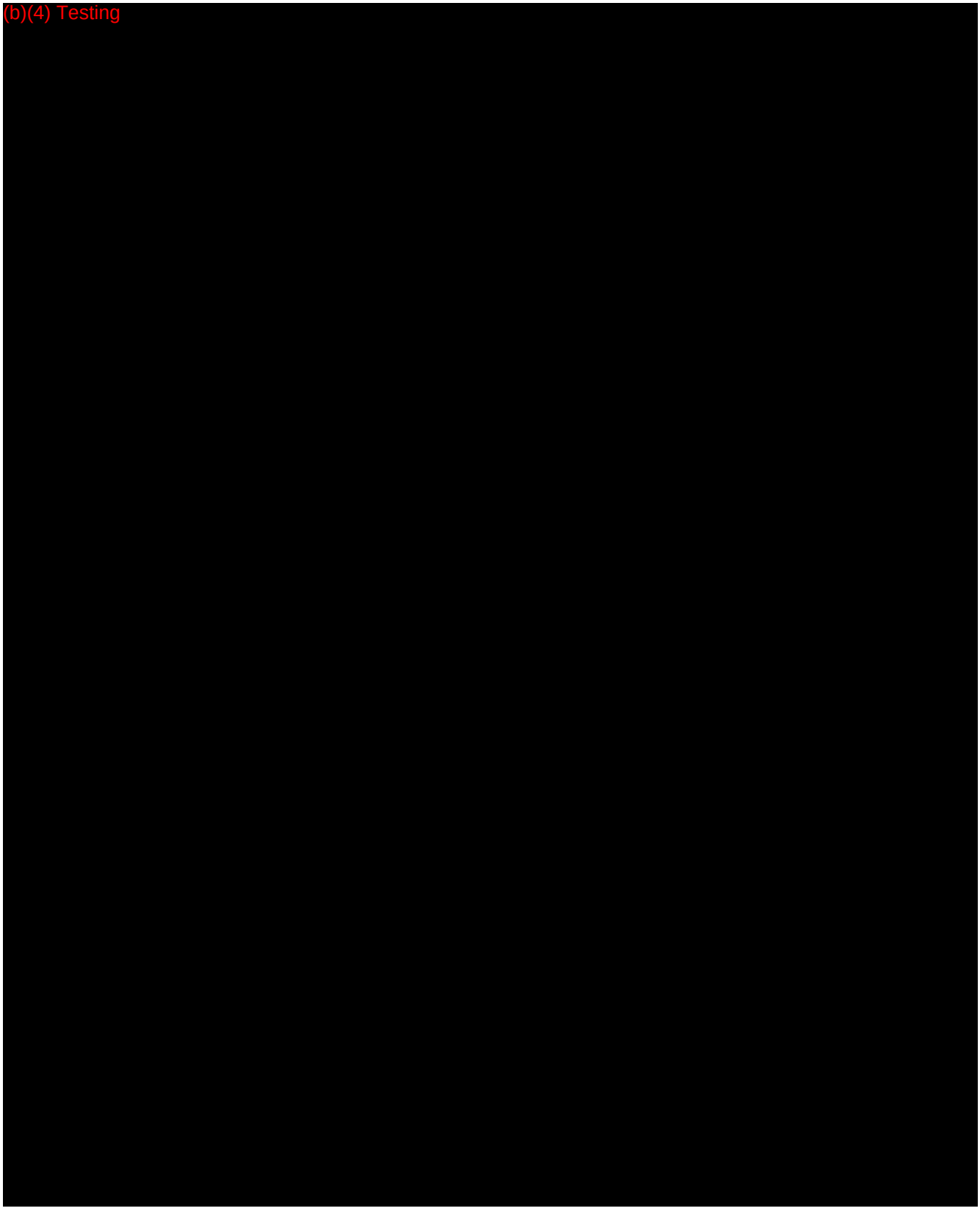


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ATTACHMENT 1

(b)(4) Testing

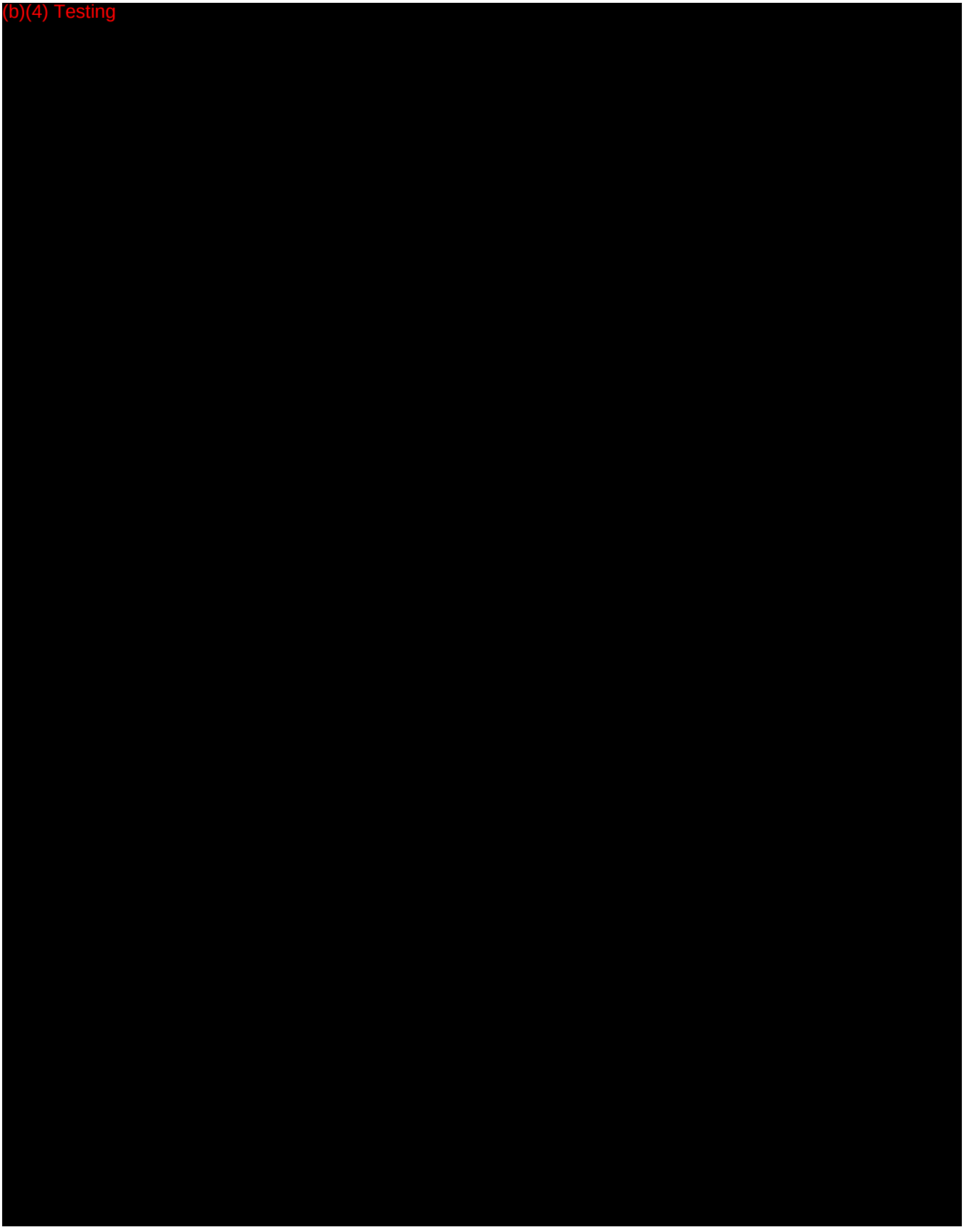


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ATTACHMENT 2

(b)(4) Testing



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(b)(4) Testing



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ATTACHMENT 3

(b)(4) Testing



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ATTACHMENT 4

(b)(4) Testing



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ATTACHMENT 5

(b)(4) Testing

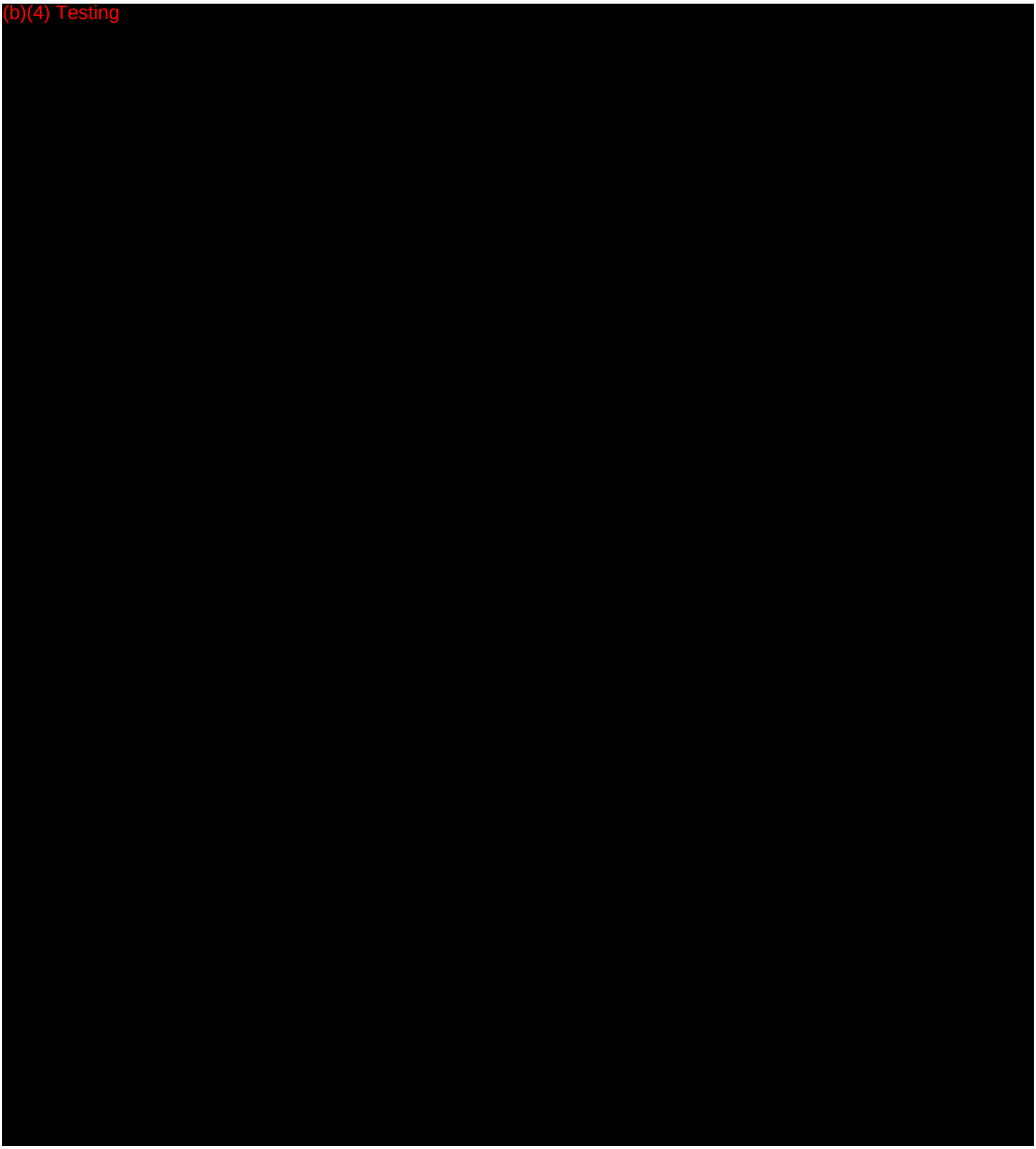


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ATTACHMENT 6

(b)(4) Testing



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(b)(4) Testing



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ATTACHMENT 7

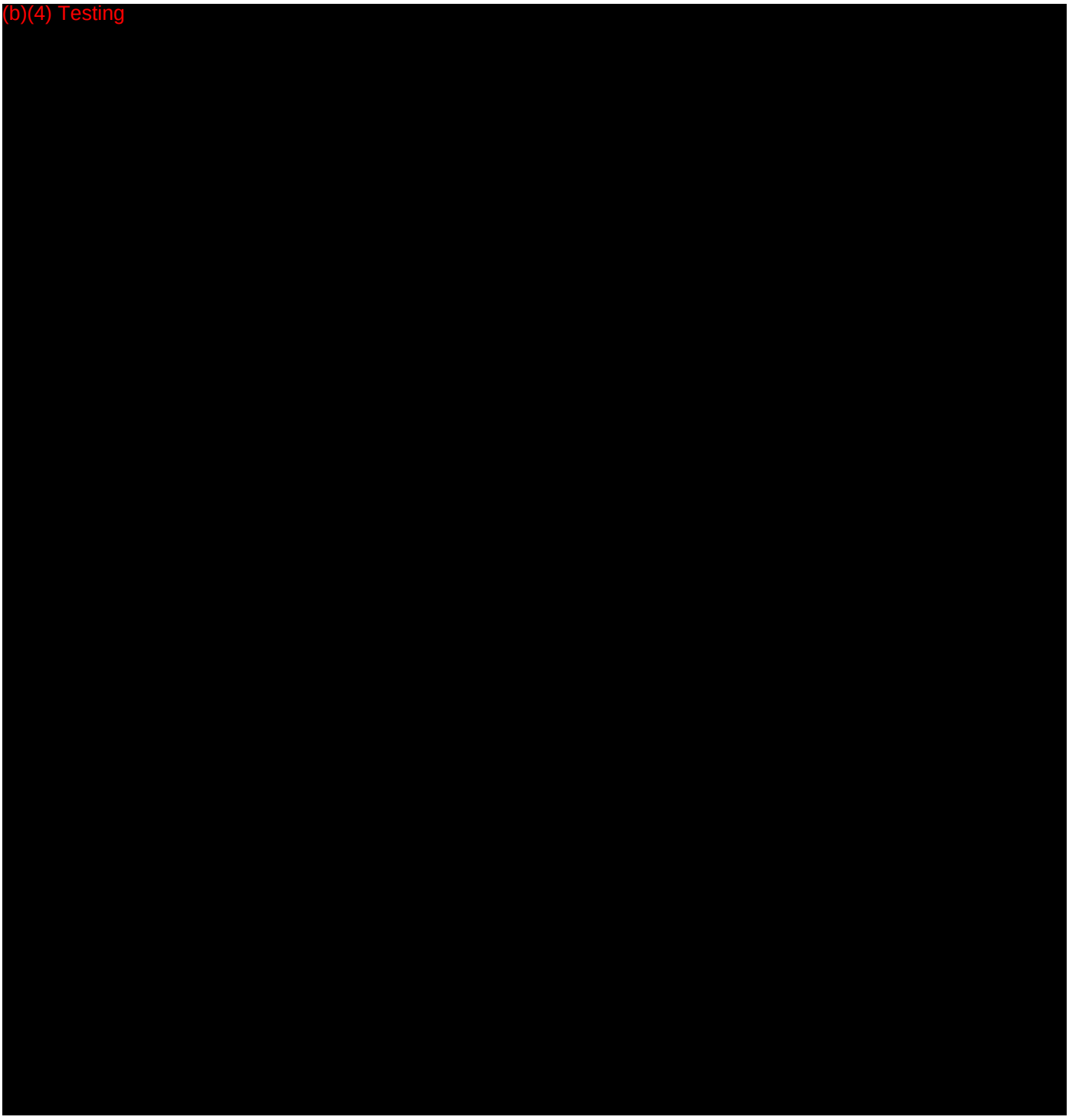
(b)(4) Testing



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ATTACHMENT 8

(b)(4) Testing



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(b)(4) Testing

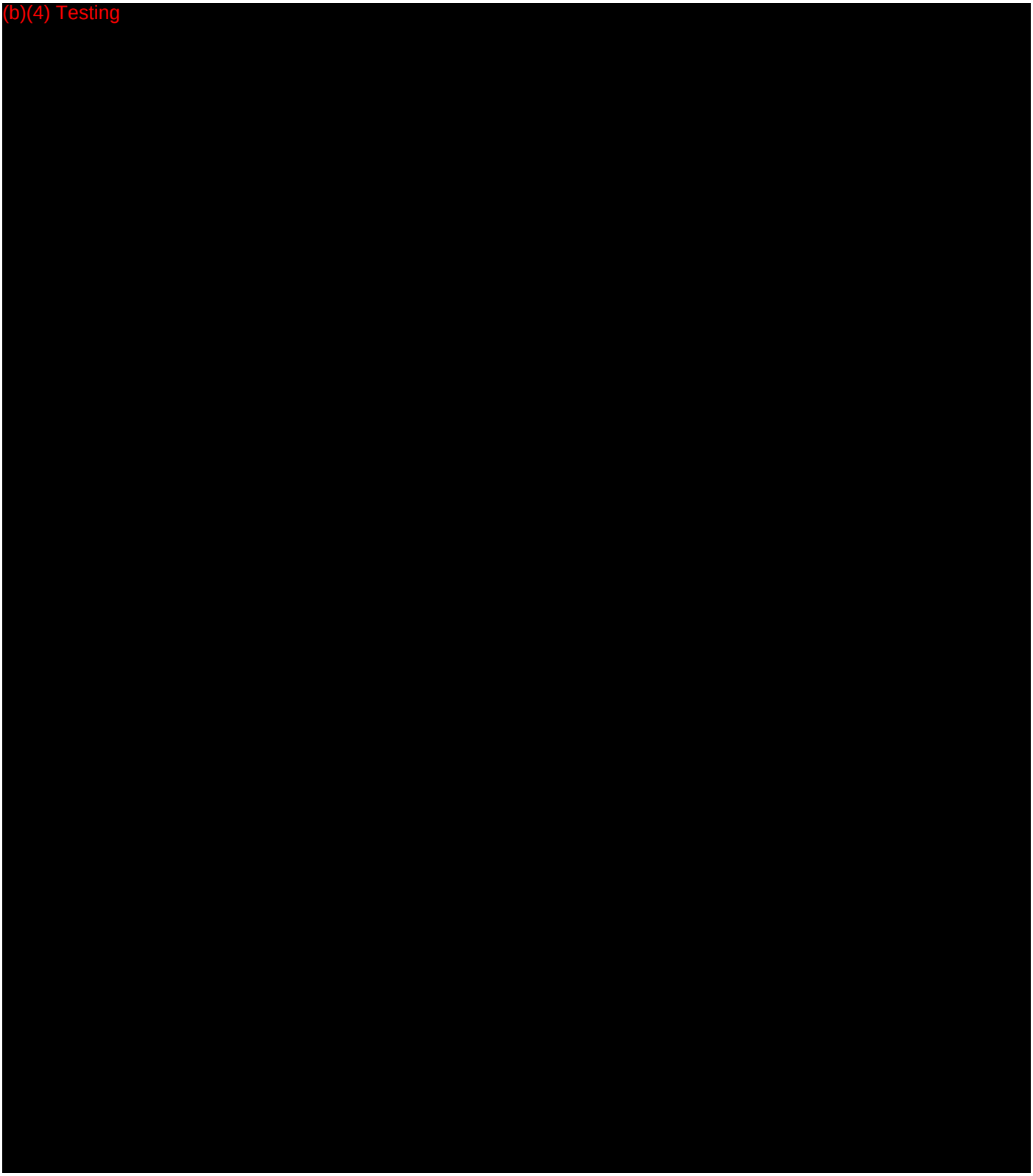
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ATTACHMENT 9

(b)(4) Testing



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(b)(4) Testing

[redacted]

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