



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 21, 2015

Abbott Vascular
Jochen Reich
Senior Regulatory Affairs Specialist
26531 Ynez Road
Temecula, California 92591

Re: K152709

Trade/Device Name: Hi-Torque Balance, Balance Middleweight, Balance Heavyweight,
Balance Trek, Balance Middleweight Universal, Balance
Middleweight Universal II, Balance Middleweight Elite Guide wires

Regulation Number: 21 CFR 870.1330

Regulation Name: Catheter Guide Wire

Regulatory Class: Class II

Product Code: DQX

Dated: September 18, 2015

Received: September 21, 2015

Dear Jochen Reich:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K152709

Device Name: HI-TORQUE BALANCE Guide Wires and HI-TORQUE BALANCE Guide Wires with Hydrocoat Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K152709

Device Name: HI-TORQUE BALANCE TREK Guide Wires with Hydrocoat Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K152709

Device Name: HI-TORQUE BALANCE HEAVYWEIGHT Guide Wires with Hydrocoat Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K152709

Device Name: HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wires and HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wires with Hydrocoat Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K152709

Device Name: HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wires
with Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K152709

Device Name: HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wires

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K152709

Device Name: HI-TORQUE BALANCE MIDDLEWEIGHT ELITE Guide Wires

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

A) HI-TORQUE BALANCE Guide Wires

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.

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|--------------------------------------|--|
| 1. <u>Submitter's Name</u> | Abbott Vascular |
| 2. <u>Submitter's Address</u> | 26531 Ynez Road, Temecula, CA 92591 |
| 3. <u>Telephone</u> | 0049-15165621396 |
| 4. <u>Fax</u> | (951) 914-0339 |
| 5. <u>Contact Person</u> | Jochen Reich |
| 6. <u>Date Prepared</u> | September 28, 2015 |
| 7. <u>Device Trade Name</u> | HI-TORQUE BALANCE |
| 8. <u>Device Common Name</u> | Coronary Guide Wire |
| 9. <u>Device Classification Name</u> | Catheter Guide Wire (DQX) |
| 10. <u>Predicate Device Name</u> | HI-TORQUE BALANCE Guide Wire (K925381, cleared February 12, 1993), HI-TORQUE BALANCE Guide Wire with Hydrocoat Hydrophilic Coating, (K973494, cleared December 12, 1997) and HI-TORQUE BALANCE Guide Wire, (K021228, cleared May 15, 2002) |

11. Device and Change Description

The HI-TORQUE BALANCE Guide Wires are available in a 0.014" outer diameter, in 175 cm and 190 cm extendable lengths, and a 300 cm exchange length. The proximal end of the 175 cm and 190 cm models are tapered to fit into the hypotube portion of the DOC Guide Wire Extension. This enables the physician to extend the working length of this guide wire to facilitate catheter exchanges. The distal tips of the guide wires are available either as a straight tip that is shapeable or as a pre shaped "J". The change being made is in the formulation of an adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The HI-TORQUE BALANCE Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE Guide Wires met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the HI-TORQUE BALANCE Guide Wire Family may be considered substantially equivalent to the predicate devices.

Bench testing and Biocompatibility testing was conducted and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

As for bench testing the tensile strength to join the distal core of the guidewire (where the tip coil is located) with the proximal core of the guidewire was conducted. The hypotube pull test verified that the hypotube joint is sufficiently strong to withstand normal tensile loading during the use of the Guide Wire in a clinical procedure.

The modified adhesive formulation was tested for biocompatibility as per the below listed biocompatibility tests:

- a. Cytotoxicity
- b. Hemolysis, direct
- c. Hemolysis, indirect
- d. Complement Activation
- e. Coagulation (PT and PTT)
- f. Sensitization
- g. Intracutaneous Toxicity (Irritation)
- h. Acute Systemic Toxicity
- i. Pyrogenicity Material Mediated (Rabbit)

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.

B) HI-TORQUE BALANCE TREK Guide Wires

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.

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|--------------------------------------|--|
| 1. <u>Submitter's Name</u> | Abbott Vascular |
| 2. <u>Submitter's Address</u> | 26531 Ynez Road, Temecula, CA 92591 |
| 3. <u>Telephone</u> | 0049-15165621396 |
| 4. <u>Fax</u> | (951) 914-0339 |
| 5. <u>Contact Person</u> | Jochen Reich |
| 6. <u>Date Prepared</u> | September 28, 2015 |
| 7. <u>Device Trade Name</u> | HI-TORQUE BALANCE TREK |
| 8. <u>Device Common Name</u> | Coronary Guide Wire |
| 9. <u>Device Classification Name</u> | Catheter Guide Wire (DQX) |
| 10. <u>Predicate Device Name</u> | HI-TORQUE BALANCE TREK Guide Wire (K991152, cleared April 29, 1999) and HI-TORQUE BALANCE TREK Guide Wire, (K021228, cleared May 15, 2002) |

11. Device Description

The HI-TORQUE BALANCE TREK Guide Wires are available in a 0.014" outer diameter, and in an 190 cm extendable length and a 300 cm exchange length. The proximal end of the 190 cm models are tapered to fit into the hypotube portion of the DOC Guide Wire Extension. This enables the physician to extend the working length of this guide wire to facilitate catheter exchanges. The distal tips of the guide wires are available either as a straight tip that is shapeable or as a pre shaped "J". The change being made is in the formulation of an adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The HI-TORQUE BALANCE TREK Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE TREK Guide Wires met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the HI-TORQUE BALANCE TREK Guide Wire Family may be considered substantially equivalent to the predicate devices.

Bench testing and Biocompatibility testing was conducted and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

As for bench testing the tensile strength to join the distal core of the guidewire (where the tip coil is located) with the proximal core of the guidewire was conducted. The hypotube pull test verified that the hypotube joint is sufficiently strong to withstand normal tensile loading during the use of the Guide Wire in a clinical procedure.

The modified adhesive formulation was tested for biocompatibility as per the below listed biocompatibility tests:

- a. Cytotoxicity
- b. Hemolysis, direct
- c. Hemolysis, indirect
- d. Complement Activation
- e. Coagulation (PT and PTT)
- f. Sensitization
- g. Intracutaneous Toxicity (Irritation)
- h. Acute Systemic Toxicity
- i. Pyrogenicity Material Mediated (Rabbit)

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.

C) HI-TORQUE BALANCE HEAVYWEIGHT Guide Wires

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.

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|--------------------------------------|--|
| 1. <u>Submitter's Name</u> | Abbott Vascular |
| 2. <u>Submitter's Address</u> | 26531 Ynez Road, Temecula, CA 92591 |
| 3. <u>Telephone</u> | 0049-15165621396 |
| 4. <u>Fax</u> | (951) 914-0339 |
| 5. <u>Contact Person</u> | Jochen Reich |
| 6. <u>Date Prepared</u> | September 28, 2015 |
| 7. <u>Device Trade Name</u> | HI-TORQUE BALANCE HEAVYWEIGHT |
| 8. <u>Device Common Name</u> | Coronary Guide Wire |
| 9. <u>Device Classification Name</u> | Catheter Guide Wire (DQX) |
| 10. <u>Predicate Device Name</u> | HI-TORQUE BALANCE HEAVYWEIGHT
Guide Wire with Hydrocoat Hydrophilic Coating
(K982083, cleared September 11, 1998) and HI-
TORQUE BALANCE HEAVYWEIGHT Guide
Wire, (K021228, cleared May 15, 2002) |

11. Device Description

The HI-TORQUE BALANCE HEAVYWEIGHT Guide Wires are available in a 0.014" outer diameter, in 175 cm and 190 cm extendable lengths, and a 300 cm exchange length. The proximal end of the 175 cm and 190 cm models are tapered to fit into the hypotube portion of the DOC Guide Wire Extension. This enables the physician to extend the working length of this guide wire to facilitate catheter exchanges. The distal tips of the guide wires are available either as a straight tip that is shapeable or as a pre shaped "J". The change being made is in the formulation of the adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The HI-TORQUE BALANCE HEAVYWEIGHT Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE HEAVYWEIGHT Guide Wires met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the HI-TORQUE BALANCE HEAVYWEIGHT Guide Wire Family may be considered substantially equivalent to the predicate devices.

Bench testing and Biocompatibility testing was conducted and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

As for bench testing the tensile strength to join the distal core of the guidewire (where the tip coil is located) with the proximal core of the guidewire was conducted. The hypotube pull test verified that the hypotube joint is sufficiently strong to withstand normal tensile loading during the use of the Guide Wire in a clinical procedure.

The modified adhesive formulation was tested for biocompatibility as per the below listed biocompatibility tests:

- a. Cytotoxicity
- b. Hemolysis, direct
- c. Hemolysis, indirect
- d. Complement Activation
- e. Coagulation (PT and PTT)
- f. Sensitization
- g. Intracutaneous Toxicity (Irritation)
- h. Acute Systemic Toxicity
- i. Pyrogenicity Material Mediated (Rabbit)

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.

D) HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wires

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. <u>Submitter's Name</u>	Abbott Vascular
2. <u>Submitter's Address</u>	26531 Ynez Road, Temecula, CA 92591
3. <u>Telephone</u>	0049-15165621396
4. <u>Fax</u>	(951) 914-0339
5. <u>Contact Person</u>	Jochen Reich
6. <u>Date Prepared</u>	September 28, 2015
7. <u>Device Trade Name</u>	HI-TORQUE BALANCE MIDDLEWEIGHT
8. <u>Device Common Name</u>	Coronary Guide Wire
9. <u>Device Classification Name</u>	Catheter Guide Wire (DQX)
10. <u>Predicate Device Name</u>	HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire (K971815, cleared July 9, 1997), HI- TORQUE BALANCE MIDDLEWEIGHT Guide Wire with Hydrocoat Hydrophilic Coating (K973494, cleared December 12, 1997) and HI- TORQUE BALANCE MIDDLEWEIGHT Guide Wire, (K021228, cleared May 15, 2002)

11. Device Description

The HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wires are available in a 0.014" outer diameter, 175 cm and 190 cm extendable lengths, and a 300 cm exchange length. The proximal end of the 175 cm and 190 cm models are tapered to fit into the hypotube portion of the DOC Guide Wire Extension. This enables the physician to extend the working length of this guide wire to facilitate catheter exchanges. The distal tips of the guide wires are available either as a straight tip that is shapeable or as a pre shaped "J". The change being made is in the formulation of the adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wires met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire Family may be considered substantially equivalent to the predicate devices.

Bench testing and Biocompatibility testing was conducted and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

As for bench testing the tensile strength to join the distal core of the guidewire (where the tip coil is located) with the proximal core of the guidewire was conducted. The hypotube pull test verified that the hypotube joint is sufficiently strong to withstand normal tensile loading during the use of the Guide Wire in a clinical procedure.

The modified adhesive formulation was tested for biocompatibility as per the below listed biocompatibility tests:

- a. Cytotoxicity
- b. Hemolysis, direct
- c. Hemolysis, indirect
- d. Complement Activation
- e. Coagulation (PT and PTT)
- f. Sensitization
- g. Intracutaneous Toxicity (Irritation)
- h. Acute Systemic Toxicity
- i. Pyrogenicity Material Mediated (Rabbit)

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.

E) HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wires

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.

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|--------------------------------------|--|
| 1. <u>Submitter's Name</u> | Abbott Vascular |
| 2. <u>Submitter's Address</u> | 26531 Ynez Road, Temecula, CA 92591 |
| 3. <u>Telephone</u> | 0049-15165621396 |
| 4. <u>Fax</u> | (951) 914-0339 |
| 5. <u>Contact Person</u> | Jochen Reich |
| 6. <u>Date Prepared</u> | September 28, 2015 |
| 7. <u>Device Trade Name</u> | HI-TORQUE BALANCE MIDDLEWEIGHT
UNIVERSAL |
| 8. <u>Device Common Name</u> | Coronary Guide Wire |
| 9. <u>Device Classification Name</u> | Catheter Guide Wire (DQX) |
| 10. <u>Predicate Device Name</u> | HI-TORQUE BALANCE MIDDLEWEIGHT
UNIVERSAL Guide Wire with Hydrocoat
Hydrophilic Coating (K013833, cleared January
16, 2002), HI-TORQUE BALANCE
MIDDLEWEIGHT UNIVERSAL Guide Wire
with Hydrocoat Hydrophilic Coating (K031678,
cleared August 26, 2003) and HI-TORQUE
BALANCE MIDDLEWEIGHT UNIVERSAL
Guide Wire, (K101011, cleared May 24, 2010) |

11. Device Description

The HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wire is a steerable guide wire available in a maximum outer diameter of 0.0137" and in lengths of 190 cm and 300 cm. The distal segment of the guide wire, up to the hypotube, is coated with hydrophilic coating to reduce friction for improved guide wire movement within the catheter. The distal tip is offered in a straight shapeable configuration and a pre-shaped "J" configuration. The proximal core has a maximum diameter of 0.0137". The proximal end of the guide wire is coated with PTFE, which reduces friction of the wire within a catheter. The BMW Universal Guide Wire is DOC® extendable in the 190 cm lengths. The change being made is to the formulation of an adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wires met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wire Family may be considered substantially equivalent to the predicate devices.

Bench testing and Biocompatibility testing was conducted and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

As for bench testing the tensile strength to join the distal core of the guidewire (where the tip coil is located) with the proximal core of the guidewire was conducted. The hypotube pull test verified that the hypotube joint is sufficiently strong to withstand normal tensile loading during the use of the Guide Wire in a clinical procedure.

The modified adhesive formulation was tested for biocompatibility as per the below listed biocompatibility tests:

- a. Cytotoxicity
- b. Hemolysis, direct
- c. Hemolysis, indirect
- d. Complement Activation
- e. Coagulation (PT and PTT)
- f. Sensitization
- g. Intracutaneous Toxicity (Irritation)
- h. Acute Systemic Toxicity
- i. Pyrogenicity Material Mediated (Rabbit)

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.

E) HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wires

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.

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|--------------------------------------|---|
| 1. <u>Submitter's Name</u> | Abbott Vascular |
| 2. <u>Submitter's Address</u> | 26531 Ynez Road, Temecula, CA 92591 |
| 3. <u>Telephone</u> | 0049-15165621396 |
| 4. <u>Fax</u> | (951) 914-0339 |
| 5. <u>Contact Person</u> | Jochen Reich |
| 6. <u>Date Prepared</u> | September 28, 2015 |
| 7. <u>Device Trade Name</u> | HI-TORQUE BALANCE MIDDLEWEIGHT
UNIVERSAL II |
| 8. <u>Device Common Name</u> | Coronary Guide Wire |
| 9. <u>Device Classification Name</u> | Catheter Guide Wire (DQX) |
| 10. <u>Predicate Device Name</u> | HI-TORQUE BALANCE MIDDLEWEIGHT
UNIVERSAL II Guide (K072460, cleared April 4,
2008). |

11. Device Description

The HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire is a steerable guide wire available in a diameter of 0.0140" and in lengths of 190 cm DOC extendable length and a 300 cm exchange length. The distal tip is offered in a straight shapeable configuration and a pre-shaped "J" configuration. The distal segment of the guide wire is coated with a new lubricious coating to improve guide wire movement in the catheter. The proximal end of the guide wire utilizes SMOOTHGLIDE coating technology. The change being made is in the formulation of an adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wires met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire Family may be considered substantially equivalent to the predicate devices.

Bench testing and Biocompatibility testing was conducted and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

As for bench testing the tensile strength to join the distal core of the guidewire (where the tip coil is located) with the proximal core of the guidewire was conducted. The hypotube pull test verified that the hypotube joint is sufficiently strong to withstand normal tensile loading during the use of the Guide Wire in a clinical procedure.

The modified adhesive formulation was tested for biocompatibility as per the below listed biocompatibility tests:

- a. Cytotoxicity
- b. Hemolysis, direct
- c. Hemolysis, indirect
- d. Complement Activation
- e. Coagulation (PT and PTT)
- f. Sensitization
- g. Intracutaneous Toxicity (Irritation)
- h. Acute Systemic Toxicity
- i. Pyrogenicity Material Mediated (Rabbit)

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.

F) HI-TORQUE BALANCE MIDDLEWEIGHT ELITE Guide Wires

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.

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| 1. <u>Submitter's Name</u> | Abbott Vascular |
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| 3. <u>Telephone</u> | 0049-15165621396 |
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| 5. <u>Contact Person</u> | Jochen Reich |
| 6. <u>Date Prepared</u> | September 28, 2015 |
| 7. <u>Device Trade Name</u> | HI-TORQUE BALANCE MIDDLEWEIGHT
ELITE |
| 8. <u>Device Common Name</u> | Coronary Guide Wire |
| 9. <u>Device Classification Name</u> | Catheter Guide Wire (DQX) |
| 10. <u>Predicate Device Name</u> | HI-TORQUE BALANCE MIDDLEWEIGHT
ELITE Guide (K103101, cleared February 10,
2011). |

11. Device Description

The HI-TORQUE BALANCE MIDDLEWEIGHT ELITE Guide Wire is a steerable guide wire available in a maximum outer diameter of 0.014" and in lengths of 190 cm and 300 cm. The distal segment of the guide wire is coated with hydrophilic coating to reduce friction for improved guide wire movement within the catheter. The distal tip is offered in a straight shapeable configuration and a pre-shaped "J" configuration. The proximal core has a maximum diameter of 0.0145". The proximal end of the guide wire is coated with hydrophobic coating, which reduces friction of the wire within a catheter. The ELITE Guide Wire is DOC® extendable in the 190 cm lengths. The change being made is in the formulation of an adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The HI-TORQUE BALANCE MIDDLEWEIGHT ELITE Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE MIDDLEWEIGHT ELITE Guide Wires met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the HI-TORQUE BALANCE MIDDLEWEIGHT ELITE Guide Wire Family may be considered substantially equivalent to the predicate devices.

Bench testing and Biocompatibility testing was conducted and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

As for bench testing the tensile strength to join the distal core of the guidewire (where the tip coil is located) with the proximal core of the guidewire was conducted. The hypotube pull test verified that the hypotube joint is sufficiently strong to withstand normal tensile loading during the use of the Guide Wire in a clinical procedure.

The modified adhesive formulation was tested for biocompatibility as per the below listed biocompatibility tests:

- a. Cytotoxicity
- b. Hemolysis, direct
- c. Hemolysis, indirect
- d. Complement Activation
- e. Coagulation (PT and PTT)
- f. Sensitization
- g. Intracutaneous Toxicity (Irritation)
- h. Acute Systemic Toxicity
- i. Pyrogenicity Material Mediated (Rabbit)

The results obtained from the biological evaluation indicate that the products do not pose any safety risks associated with its introduction into the body and that materials selected for manufacture of these products are appropriate for the intended use.