K082385

510(k) Summary

DEC 11 2008

Trade Name: Chaperon Guiding Catheter System

Generic Name: Percutaneous Catheter

Classification: Class II, 21 CFR 870.1250

Submitted By: MicroVention, Inc
75 Columbia
Aliso Viejo, California U.S.A.

Contact: Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K070970	Penumbra Inc., Neuron Intracranial Access System	Chaperon Guiding Catheter System	August 17, 2007

Device Description

The Chaperon Guiding Catheter system is designed to advance interventional and diagnostic devices through the vasculature. The device is intended for general intravascular use, including the neuro and peripheral vasculature. The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035 in or a 0.038 in guidewire or together with the Inner Catheter to access the desired anatomy.

Indication For Use

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

Verification and Test Summary Table

Bench Testing	Result
Surface Contamination & Tip Configuration	Met established criteria
Dimensional Inspection & Physical Attributes	Met established criteria
Tensile Strength	Met established criteria
Hub Attachment Strength	Met established criteria
Tip Attachment Strength	Met established criteria
Freedom from Leakage – Fluid & Air	Met established criteria
Leak Test (High Static Pressure)	Met established criteria
Hub Gauging	Met established criteria
Separation Force	Met established criteria
Stress Cracking	Met established criteria
Screwing Torque	Met established criteria
Ease of Assembly	Met established criteria
Resistance to Overriding	Met established criteria
Flow Rate	Met established criteria
Radio-Detectability	Met established criteria
Catheter Burst & Leakage	Met established criteria
Stiffness & Kink Resistance	Met established criteria
Durability & Lubricity & Fatigue	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Chaperon Guiding Catheter System compared with the predicate device Penumbra Neuron Intracranial Access System (K070970).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same processes.

In summary, the Chaperon Guiding Catheter System described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardiovascular Systems, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

DEC 11 2008

Re: K082385
Chaperon Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 11, 2008
Received: November 12, 2008

Dear Mr. Job:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

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): _____

Device Name: Chaperon Guiding Catheter System

Indications for Use:

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052385

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

Microvention, Inc.
c/o Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K082385
Trade/Device Name: Chaperon Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 11, 2008
Received: November 12, 2008

Dear Mr. Job:

This letter corrects our substantially equivalent letter of December 11, 2008.

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 (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.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/cdrh/dsma/dsmamain.html

Sincerely yours,

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): _____

Device Name: Chaperon Guiding Catheter System

Indications for Use:

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062385

3

Department of Health and Human Services

Memorandum

Food & Drug Administration
Center of Device & Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Date: December 11, 2008
From: Kenneth J. Cavanaugh, Jr., Ph.D., Acting Chief
FDA/CDRH/ODE/DCD/PVDB

Subject: Third-party review of K082385

Device Name:	Chaperon Guiding Catheter
Product Code:	DQY
Regulation:	21 CFR 870.1250 (Class II)
Manufacturer:	MicroVention, Inc.
Contact:	Mark Job Reviewer Regulatory Technical Services 1394 25th Street NW Buffalo, MN 55313 Phone: (763) 682-4139 Fax: (763) 682-4420

Background:
This device was cleared (SE) on December 11, 2008. The clearance letters did not include the correct name of the manufacturer. A correction letter containing the correct manufacturer name was prepared.

12/11/08

4

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
450	Caum	12/11/08						
Z-450	Kuhner	12/11/08						
	for BDZ							

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

Last Updated: Brandi Stuart 8/16/07

Division of Enforcement A	Betty W. Collins	240-276-0115
Deputy Director	George Kroehling	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	Ronald L. Swann	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	Paul Tilton	240-276-0115
General Hospital Devices Branch	Valerie Flournoy	240-276-0115
General Surgery Devices Branch	Thomas Knott	240-276-0115
Division of Enforcement B	Gladys Rodriquez	240-276-0120
Deputy Director	Christy Foreman	240-276-0120
Cardiovascular & Neurological Devices Branch	Nicole Wolanski	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Branch	William MacFarland	240-276-0120

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardiovascular Systems, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

DEC 11 2008

Re: K082385
Chaperon Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 11, 2008
Received: November 12, 2008

Dear Mr. Job:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

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): _____

Device Name: Chaperon Guiding Catheter System

Indications for Use:

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062385

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 12, 2008

MICROVENTION, INC.
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
UNITED STATES
ATTN: MARK JOB

510k Number: K082385

Product: CHAPERON GUIDING CATHETER

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 (HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html. 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/cdrh/ode/guidance/1567.html. 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.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 2008

Microvention, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K082385
Chaperon Guiding Catheter
Dated: September 22, 2008
Received: September 23, 2008

Dear Mr. Job:

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.

In response to deficiency #1 of FDA's September 8, 2008 letter, you provided additional information on the testing that was conducted using the tortuous benchtop silicone model. You have also provided scientific literature with information on the usage of tortuous models. Although this information provides additional details into the methods of your testing, FDA believes animal data are essential to evaluate whether the safety of your device is substantially equivalent to the safety of the predicates. Please provide histological data obtained from animal studies demonstrating that your device is atraumatic to the neurovasculature. Alternatively, you may remove the neurovascular indication from the scope of this 510(k) submission.

The deficiency identified above represents the issue that we believe needs to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiency, 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.

We also considered the burden that may be incurred in your attempt to respond to the deficiency. We believe that we have considered the least burdensome approach to resolving this issue. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document titled "A Suggested Approach to Resolving Least Burdensome Issues" located at http://www.fda.gov/cdrh/modact/leastburdensome.html

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, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

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. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Dr. Kenneth Cavanaugh at (240) 276-4177. 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kenneth J. Cavanaugh Jr., Ph.D.
Acting Chief, Peripheral Vascular
Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Microvention, Inc.
c/o Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

SEP 18 2008

Re: K082385
Trade Name: Chaperon Guiding Catheter
Dated: August 18, 2008
Received: August 19, 2008

Dear Mr. Job:

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:

(b)(4)

[redacted]

(b)(4)

[redacted]

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.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document titled "A Suggested Approach to Resolving Least Burdensome Issues" located at http://www.fda.gov/cdrh/modact/leastburdensome.html

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, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

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. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Dr. Kenneth Cavanaugh at (240) 276-4177. 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kenneth J. Cavanaugh Jr., Ph.D.
Acting Chief, Peripheral Vascular
Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

(Please include 510(k) number here: K082385)

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
450	Gaumay	9/8/08						

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

Last Updated: Brandi Stuart 7/31/08

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 19, 2008

MICROVENTION, INC.
c/o REGULATORY TECHNOLOGY SERVICES,
1394 25TH STREET, NW
BUFFALO, MN 55313
ATTN: MARK JOB

510(k) Number: K082385
Received: 19-AUG-2008
Product: CHAPERON GUIDING CATHETER

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)(HFZ-401) 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/cdrh/mdufma/index.html 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/opacom/morechoices/fdaforms/FDA-3654.pdf.

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/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued

a draft guidance titled: "Certifications To Accompany Drug, Biological 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/oc/initiatives/fdaaa/guidance_certifications.html). 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/cdrh/ode/guidance/1655.pdf. 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 www.fda.gov/cdrh/ode/guidance/1567.html. 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 www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K082385

Date: August 18, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: New Device

B. Name and Address of the Third Party:

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

C. Name and Address of the Manufacturer:

MicroVention, Inc.
75 Columbia, Suite A
Aliso Viejo, CA 92656

CU
II

D. Device Name

Trade or Proprietary Name: Chaperon Guiding Catheter

Classification Name: Percutaneous Catheter

Regulation Number: 21 CFR 870.1250

Recommendation: Substantially Equivalent

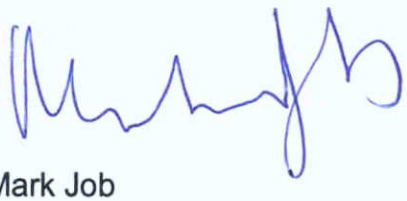
Date Submission was received by
Regulatory Technology Services LLC: August 12, 2008

We have enclosed the following materials:

E. Authorization Letter from the applicant (MAL-F-0006).
F. Complete 510(k) application submitted by the applicant.
G. Documented review of the 510(k) application (RPP-F-0012, RPP-F-14 and all correspondence and documents related to the review).
H. Conflict of Interest Certification (COI-F-0018)
I. Certification (RPP-F-0020)

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,



Mark Job
Responsible Third Party Official

Submission Certification

1. I certify that Regulatory Technology Services LLC continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by the FDA;

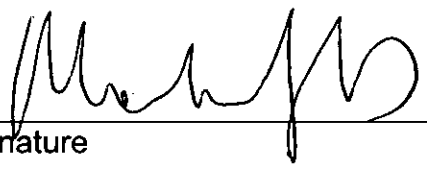
2. In addition, I state that Regulatory Technology Services LLC believes that statements made in the review are true and accurate to the best knowledge of Regulatory Technology Services LLC;

3. Regulatory Technology Services LLC's review is based on the 510(k) that is attached with the review; and

4. Regulatory Technology Services LLC understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 33(q).

Mark Job

Print Name of Accredited Person Responsible Official



Signature

Date: August 18, 2008

510(k) Summary

Trade Name: Chaperon Guiding Catheter System

Generic Name: Percutaneous Catheter

Classification: Class II, 21 CFR 870.1250

Submitted By: MicroVention, Inc
75 Columbia
Aliso Viejo, California U.S.A.

Contact: Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K070970	Penumbra Inc., Neuron Intracranial Access System	Chaperon Guiding Catheter System	August 17, 2007

Device Description

The Chaperon Guiding Catheter system is designed to advance interventional and diagnostic devices through the vasculature. The device is intended for general intravascular use, including the neuro and peripheral vasculature. The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035 in or a 0.038 in guidewire or together with the Inner Catheter to access the desired anatomy.

Indication For Use

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

Verification and Test Summary Table

Bench Testing	Result
Surface Contamination & Tip Configuration	Met established criteria
Dimensional Inspection & Physical Attributes	Met established criteria
Tensile Strength	Met established criteria
Hub Attachment Strength	Met established criteria
Tip Attachment Strength	Met established criteria
Freedom from Leakage – Fluid & Air	Met established criteria
Leak Test (High Static Pressure)	Met established criteria
Hub Gauging	Met established criteria
Separation Force	Met established criteria
Stress Cracking	Met established criteria
Screwing Torque	Met established criteria
Ease of Assembly	Met established criteria
Resistance to Overriding	Met established criteria
Flow Rate	Met established criteria
Radio-Detectability	Met established criteria
Catheter Burst & Leakage	Met established criteria
Stiffness & Kink Resistance	Met established criteria
Durability & Lubricity & Fatigue	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Chaperon Guiding Catheter System compared with the predicate device Penumbra Neuron Intracranial Access System (K070970).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same processes.

In summary, the Chaperon Guiding Catheter System described in this submission is, in our opinion, substantially equivalent to the predicate device.

Indications for Use

510(k) Number (if known): _____

Device Name: Chaperon Guiding Catheter System

Indications for Use:

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

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

Conflict of Interest Declaration and Certification For the review of the 510(k) submission from

Applicant: MicroVention, Inc.

Device Name or Model Name: Chaperon Guiding Catheter

Initials

I have read and understand Regulatory Technology Services LLC's Conflict of interest and Confidentiality Procedure (COI-S-0023), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

I have not been employed within the last two years by the firm who submitted the 510(k) for evaluation.

I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

I have not performed testing in connection with this specific device 510(k).

I understand that the Accredited Persons (AP) Program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.

I do not participate in the design, manufacture or distribution of any medical device.

I do not provide consultative services to any device manufacturer or distributor regarding specific devices.

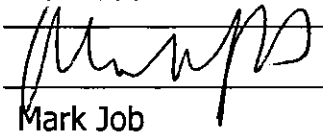
Signed: _____

Printed Name: Mark Job

Date: August 12, 2008

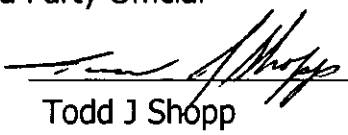
510(k) Applicant's Name: **MicroVention, Inc.**

Primary Reviewer: Mark Job

Signature:  Date: August 18, 2008

Print Name: Mark Job Title: Reviewer

Responsible Third Party Official

Signature:  Date: August 18, 2008

Print Name: Todd J Shopp Title: Program Supervisor

Regulatory Technology Services LLC

	Yes*	No*	
1. Is product a device?	X		If NO= Stop
2. Is device subject to 510(k)?	X		If NO= Stop
3. Same indication statement?	X		If YES=Go to 5
4. Do differences alter the effect or raise new issues of safety or effectiveness?			If YES=Stop NE
5. Same technological characteristics?	X		If YES=Go to 7
6. Could the new characteristics affect safety or effectiveness?			If YES=Go to 8
7. Descriptive characteristics precise enough?		X	If NO=Go to 10 If YES=Stop
8. New types of safety or effectiveness questions?			If YES=Stop NE
9. Accepted scientific methods exist?			If NO=Stop NE
10. Performance data available?	X		If NO=Request Data
11. Data demonstrate equivalence?	X		Final Decision: **SE**

*Note: In Addition to completing page 2, "yes" responses to questions 4,6,8, and 11, and every "no" response requires an explanation on page 8. Document the decision path by marking the arrows followed on the FDA flowchart.

1. Intended Use: The MicroVention, Inc. Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries. The indications for use form provided on page 12 of the submission.

2. *Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain a drug or a biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties, and toxicology profile if important.*

Summary:

Submission Information

This submission has been submitted by MicroVention, Inc. Chaperon Guiding Catheter as a new device.

Administrative Information

A Truthful and Accuracy Statement is included on page 9. A 510(k) Summary is included on pages 10 and 11.

Reason for the Submission

This is a new device.

Device Classification

This device is classified under 21CFR870.1250 under product code DQY.

Intended Use

The MicroVention, Inc. Chaperon Guiding Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries. This statement included in the 510(k) summary is also in

line with the user manual and the indications for use form. This statement is comparable to the predicate device intended use statements.

Device Description

The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035 in or a 0.038 in guidewire or together with the Inner Catheter to access the desired anatomy.

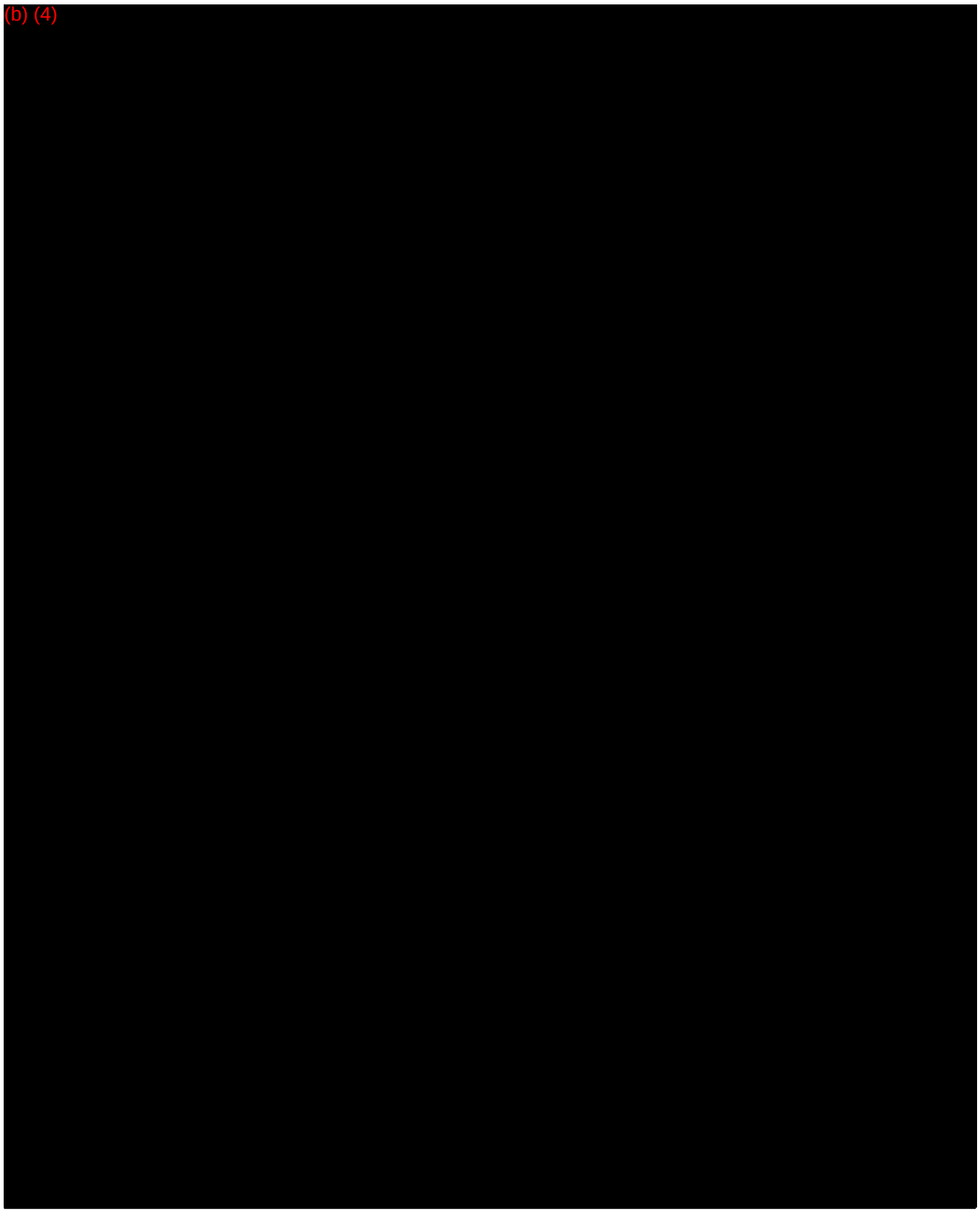
Guiding Catheter - (b) (4)

Inner Catheter - (b) (4)

Biocompatibility

(b) (4)

(b) (4)



(b) (4)

[redacted]

Sterilization

(b) (4)

[redacted]

Device Performance

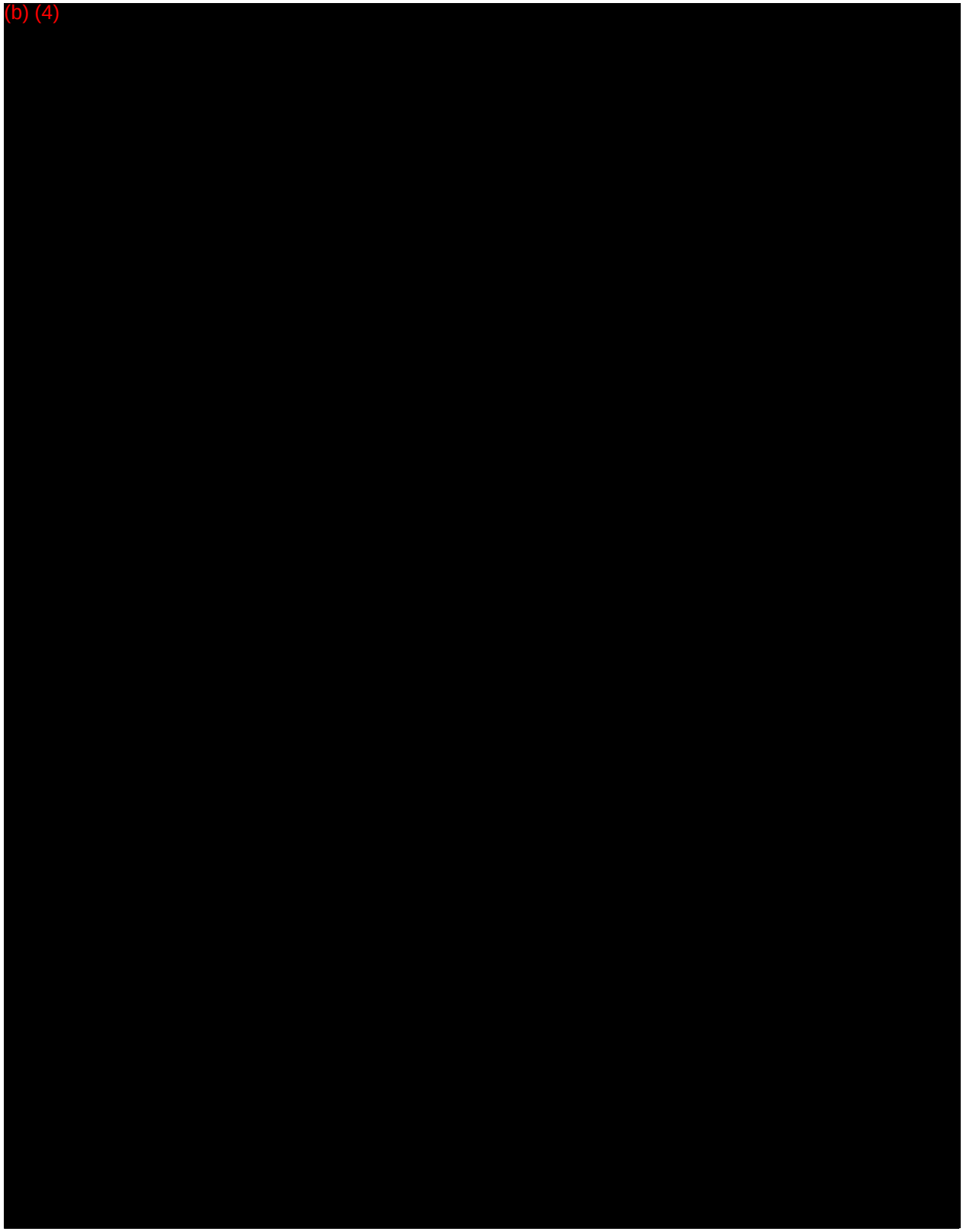
(b) (4)

[redacted]

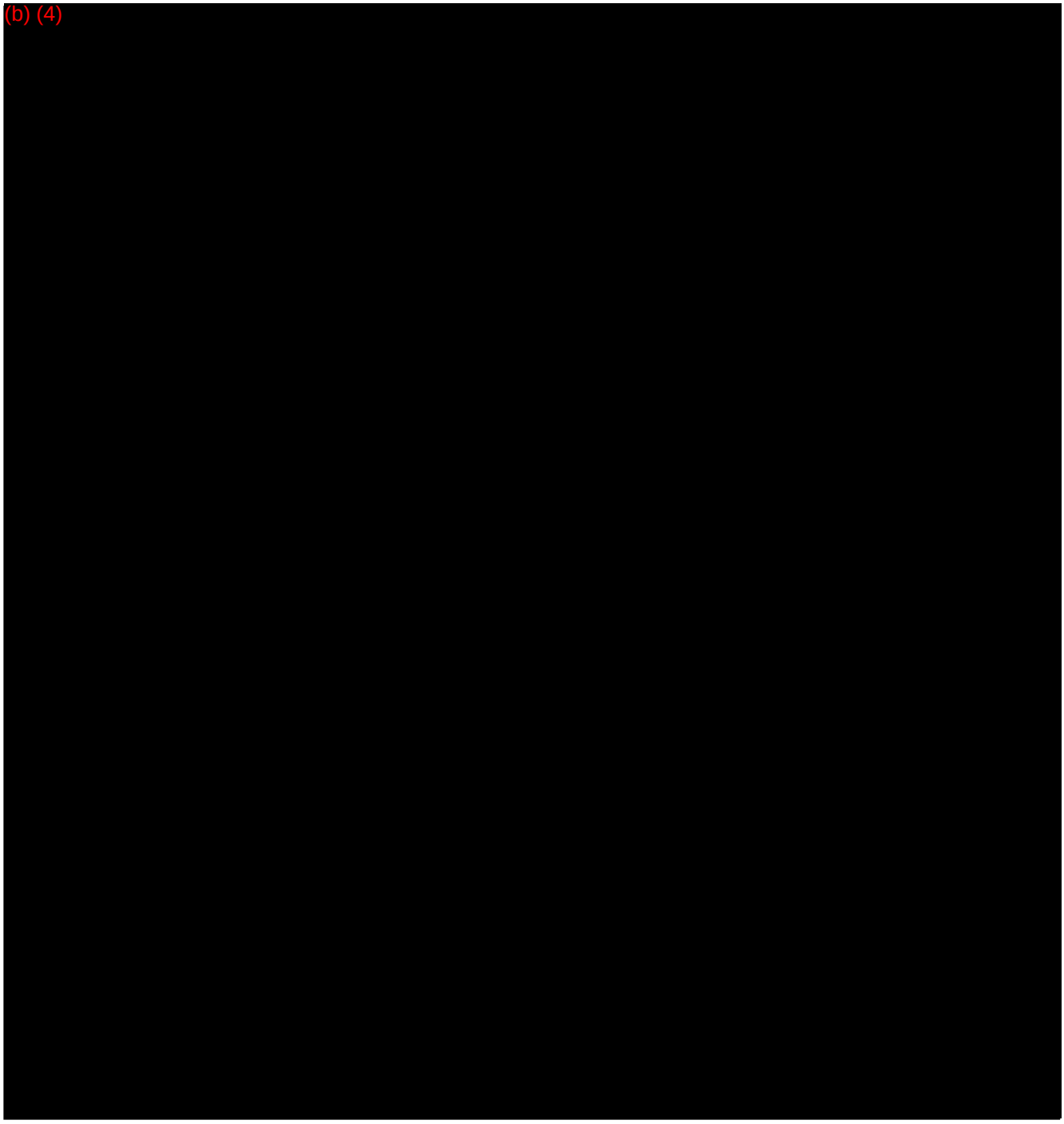
(b) (4)

[redacted]

(b) (4)



(b) (4)



(b) (4)

(b) (4)

[redacted]

Conclusion: The Chaperon Guiding Catheter is similar to the predicate device with regards to intended use, performance parameters, features and materials. The Chaperon Guiding Catheter is substantially equivalent to the predicate device. The comparison does not raise any new concerns or questions related to the safety and effectiveness.

Proposed Device Labeling

The submission includes labeling (TAB 1) which includes labels on the device, instructions for use and a package labels. The labels on the device include warnings and indication which allow an intuitive user to understand the operation of the device. The labeling includes the intended use, the prescription statement, warnings, cautions, precautions, contraindications, directions for use, maintenance, and cleaning instructions. The labeling meets the requirements of the bluebook memo.

Reviewer's Analysis

As the reviewer of this submission I have reviewed the instructions for use, the submitter's description of the device and compared this information against the information concerning the predicate devices provided by the submitter. The specifications, features, intended use, safety features, etc. for the predicate device and the new device have been compared. The differences are considered to be minimal in relationship to the previously cleared device and the new device application and intended use. The labeling included in the submission was reviewed. There are no new questions of safety and effectiveness raised during this review.

Reviewer's Recommendation

Based upon the above summary, a substantially equivalent decision is recommended.

Classification Name: Percutaneous Catheter
Regulatory Class: II
Product Code: DQY
Classification Number: 21 CFR 870.1250

Explanations To "Yes" and "No" Answers to Questions On Page 1 As Needed.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6: Explain how new characteristics could or could not affect safety or effectiveness:

7: Explain how descriptive characteristics are not precise enough: **The descriptive characteristics can not demonstrate the effectiveness.**

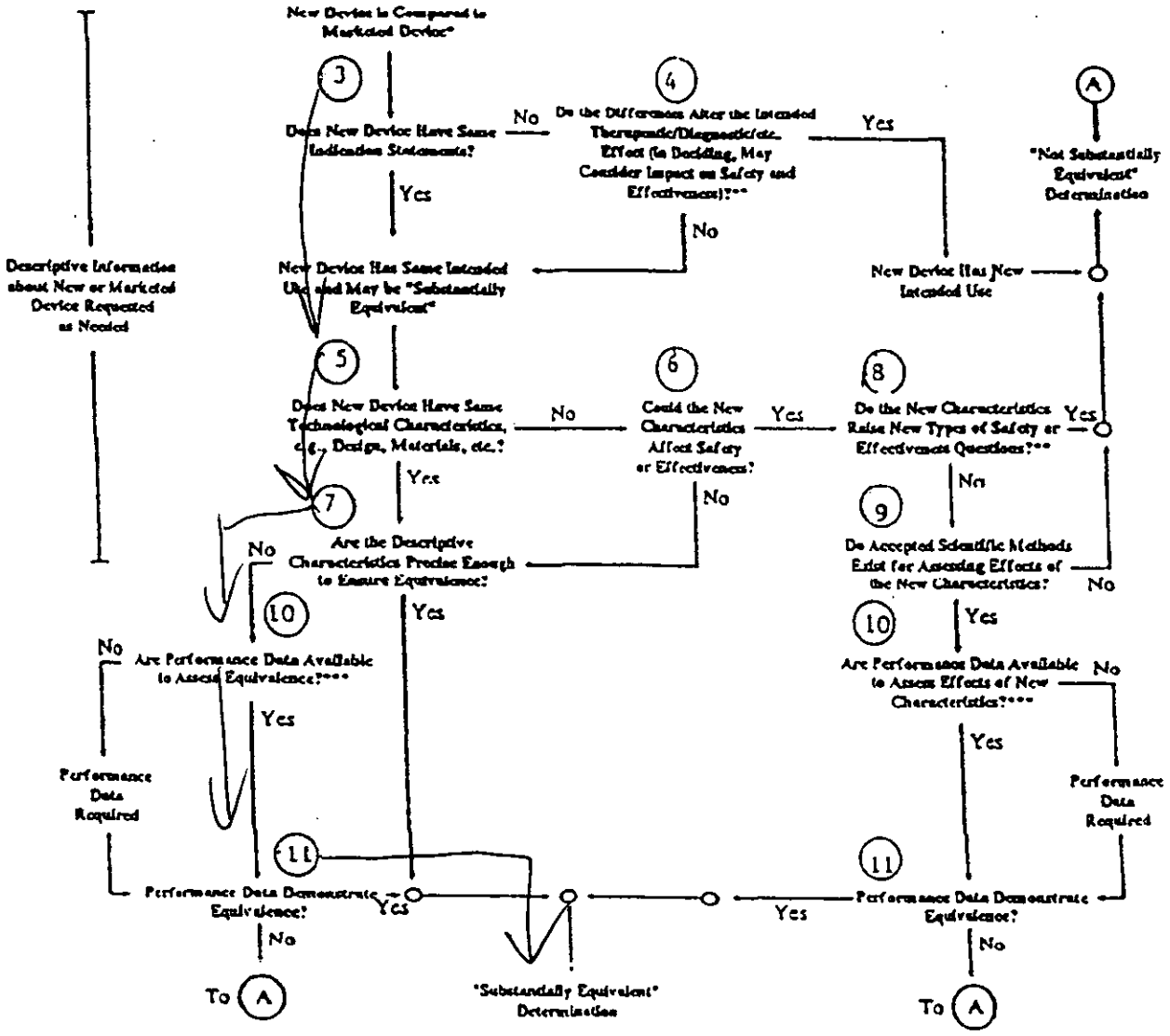
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed: **Bench performance data provided in the submission beginning on page 27.**

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: **The bench data provided demonstrates the device performs as designed. See discussion above.**

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

NOTE TO THE FDA REVEIWERS

The following information attached to this document is considered an internal document and is confidential. This document may contain information from other reviews performed by this reviewer, other sponsor information which is not related to this subject device, discussions between a Regulatory Technology Services LLC reviewer and a FDA reviewer which are not the same sponsor, etc. ALL information included in this document has not been distributed outside organization of Regulatory Technology Services LLC during this review. This information is included merely as a method to maintain a complete record of previous discussions related to this same type of device.

CONFIDENTIAL

Summary of Discussion with Branch Chief

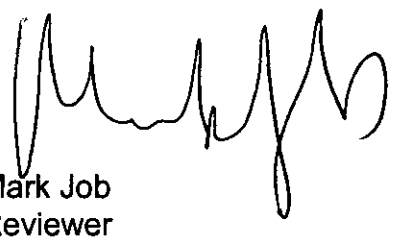
Date:	December 14, 2006	FDA Branch:	Cardiovascular
Reviewer:	Mark Job	FDA Reviewer	Tara Ryan
Review	Amplatzer Catheter Delivery System		

The following is a record of the discussion between the reviewer and the branch chief.

The following email from Tara Ryan includes the necessary requirements for completing a review of a device included in the list of expansion devices which do not have a guidance document available. This email exchange includes all of the necessary elements to summarize the requirements for Regulatory Technology Services LLC to complete the review of this submission.

NOTE: Due to the knowledge of this device by this reviewer no contact was made with the Cardiovascular Branch. The content from the previous submission is included to assure continuity. This device is an accessory to the previously review and cleared device. Contact is not required.

August 11, 2008



Mark Job
Reviewer

(b) (4) Proprietary Information

(b) (4) Proprietary Information

(b) (4) Proprietary Information

(b) (4) Proprietary Information

Part Acceptance / Non-acceptance

1. Accredited Person:

Name: Regulatory Technology Services LLC

Address 1394 25th Street NW

Buffalo, MN 55313

Contact: Mark Job

Telephone: 763 682 4139 Fax: 763 682 4420

2. Foreign Accredited Person, Specify a Domestic Correspondent:

Name: Not Applicable

Address

Contact:

Telephone: Fax:

3. 510(k) Owner (Applicant, Manufacturer, other persons preparing 510(k))

Name: MicroVention, Inc.

Address 75 Columbia, Suite A

Aliso Viejo, CA 92656

Contact: Florin Truuvert

Telephone: 949 951 0516 Fax: 949 349 1360

STOP!

Before completing items 4 to 9 below, complete pages 3 – 6 of this document.

4. Device Name:

Trade or Proprietary Name: Chaperon Guiding Catheter System

Classification Name: Percutaneous Catheter

5. CFR Classification Citation: 21 CFR 870.1250 (see 21 CFR 862 through 892)

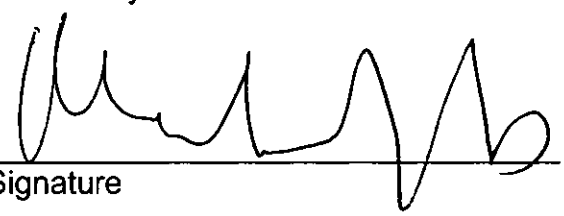
6. Classification Panel: Cardiovascular

7. Based on my completion of this document, I recommend that this 510(k):

☒ Be accepted for substantive review and I have notified the 510(k) owner using RPP-F-0016.

☐ Not be accepted for substantive review and I have listed the deficiencies on RPP-F-0016.

8. Primary Reviewer



Signature

August 12, 2008

Date

Mark Job

Print Name

9. Supervisor

Signature

8/18/08

Date

Todd J Shopp

Print Name

Checklist Questions:	YES	NO	Instructions
1. a). Is the device one that FDA has determined as being acceptable for third party review?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
1 b). Have you confirmed that the manufacturer has not engaged in forum shopping?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
2. Is the device trade or proprietary name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
3. Is the device common or usual name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
4. Is the device classification name, class of the device, and regulation number (21 CFR 870.1250 included?	☒	☐	If NO, note deficiency on RPP-F-0013.
5. Is the classification panel included?	☒	☐	If NO, note deficiency on RPP-F-0013.
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	☒	☐	If NO, note deficiency on RPP-F-0013.
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	☒	☐	If NO, note deficiency on RPP-F-0013.
8. Does the submission contain the "Indications for Use" form?	☒	☐	If YES, indicate page number 12. If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
9. Does the submission contain an acceptable 510(k) Summary of Safety and Effectiveness (per 21 CFR 807.92) OR an acceptable 510(k) Statement (per 21 CFR 807.93) that safety and effectiveness information will be made available to any person upon request?	☒	☐	If YES, indicate page number 16-11 If NO, note deficiency on RPP-F-0013.
10. Does the submission contain photographs of the device if applicable?	☐ N/A	☐	If NO, note deficiency on RPP-F-0013.
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	☒	☐	If NO, note deficiency on RPP-F-0013.
12. Does the submission identify the device to which equivalence is claimed?	☒	☐	
13. If the answer to question 12 is YES, did the applicant identify:			
a. Predicate device (referred to as marketed device)?	☐	☒	
b. Legally marketed device (referred to as marketed device)?	☒	☐	Note deficiency on RPP-F-0013.
Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a pre-amendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA has determined is SE to another marketed device (21 CFR 807.92(a)3). IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE. If it is not, the review must STOP. Telephone DSMA for assistance.			List all 510(k) control numbers: K070970

Checklist Questions:	YES	NO	Instructions
14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?	☒	☐	If NO, note deficiency on RPP-F-0013.
15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)	☒	☐	If NO, note deficiency on RPP-F-0013.
16. Does the submission contain the Truthful and Accurate Statement (per 21 CFR 807.87(j))?	☒	☐	If YES, indicate page number 9. If NO, note deficiency on RPP-F-0013.
17. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
18. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and fax number?	☐ N/A	☐	If NO, note deficiency on RPP-F-0013.
19. Does the submission contain a table of contents with pagination?	☒	☐	If NO, note deficiency on RPP-F-0013.
20. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?	☒	☐	If NO, note deficiency on RPP-F-0013.
21. Does the submission contain a comparison table of the new device to the marketed device?	☒	☐	If NO, note deficiency on RPP-F-0013.
22. Does the submission contain information about the action taken to comply with voluntary standards?	☒	☐	If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
23. Does the submission contain performance data (can be bench or animal but not clinical), i.e.: Is there performance data for the marketed device? a. Bench testing? b. Animal testing?	☒ N/A	☐ ☐	If NO, note deficiency on RPP-F-0013.
Is there performance data for the new device? a. Bench testing? b. Animal testing?	☒ N/A	☐ ☐	If NO, note deficiency on RPP-F-0013.
24. If the device is labeled as sterile, does the submission contain sterilization data?	☒	☐	If NO, note deficiency on RPP-F-0013.
25. Does the device incorporate a computer or computer software? a. If YES, is there information about the hardware? b. If YES, is there information about the software?	☐ N/A ☐ N/A ☐ N/A	☐ ☐ ☐	If NO, note deficiency on RPP-F-0013.
26. a) Is there a specific guidance document for this type of device? Title: _____ _____	☐	☒	If YES, continue review with checklist from the specific guidance document and return to question 27. If NO, proceed to question 26 b).
26 b) Contact the appropriate ODE Branch Chief to obtain information for reviewing this type of device. Has a summary of this discussion been documented?	☒	☐	If YES, answer question 27. If NO, do not proceed to question 27; stop review until summary completed.
27 Is this 510(k) sufficiently complete to allow substantive review?	☒	☐	If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms. If NO, note deficiency on RPP-F-0013.

Authorization Form

Regulatory Technology Services LLC

Date: Aug 8, 2008

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: Authorization for Accredited Person Review of 510(k)

To Whom It May Concern:

Enclosed is the Premarket Notification 510(k) for the following product: Chaperon Guiding Catheter manufactured by MicroVention Inc.

We at MicroVention Inc., (*name of manufacturer*) hereby authorize Regulatory Technology Services LLC to submit the enclosed 510(k) to the Food and Drug Administration (FDA) on our behalf, discuss its contents with the FDA, and function as the Accredited Person to perform the third party review.

We certify, we have not established a contract with another Accredited Person to perform the review of this 510(k) submission.

We accept the quote for 510(k) review services including the Regulatory Technology Services LLC Terms and Conditions.

Sincerely,

Florin Trouvent
Director, Regulatory Affairs

Signature and
Name of Manufacturer Representative

MICROVENTION®
TERUMO
ingenuity. for life.

Food and Drug Administration
Center for Devices and Radiologic Health
Office of Device Evaluation
Document Mail Center **(HFZ-401)**
9200 Corporate Boulevard
Rockville, MD 20850

August 8, 2008

RE: Traditional 510(k) Notification: Chaperon Guiding Catheter System - Predicate to Penumbra Inc., Neuron Intracranial Access System (K070970)
Classification: II
Regulation Number: 870.1250
Product Code: DQY
Classification Advisory Committee: Cardiovascular

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act as amended by the Medical Device Amendment of 1976, MicroVention, Inc. hereby submits this Traditional Premarket Notification 510(k) for Chaperon Guiding Catheter System. The Catheter System is a two catheter system comprised of a guiding (outer) catheter and an inner catheter. The device has been designed, developed and tested according to the FDA special control guidance document: Short-Term and Long-Term Intravascular Catheter and the ISO 10555.

We believe the Chaperon Guiding Catheter has the same fundamental scientific technology, basic design, operating principle and intended use as the predicate device, Neuron Intracranial Access System (K070970).

Statement of Confidentiality: MicroVention, Inc. considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of MicroVention, Inc. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (949) 951-0516.

Aug 8, 2008
Date

Florin Truuvert
Director, Regulatory Affairs
Tel: (949) 951-0516
Fax: (949) 349-1360
florint@microvention.com

Table of Contents

(b) (4)

[redacted]

Attachments

Page

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
8/8/2008		

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)*		
MicroVention, Inc.	2032493		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(949) 951-0516		
Street Address	FAX Number *(including area code)*		
75 Columbia, Suite A	(949) 349-1360		
City	State / Province	ZIP/Postal Code	Country
Aliso Viejo	CA	92656	USA
Contact Name			
Florin Truuvert			
Contact Title	Contact E-mail Address		
Director, Regulatory Affairs	florint@microvention.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/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

- ☐ 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
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

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

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

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ 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

- ☐ Repose 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)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DQY	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K070970	1	Neuron Intracranial Access System	1	Penumbra Inc.,
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Percutaneous Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Chaperon Guiding Catheter System	1	
2		2	
3		3	
4		4	
5		5	

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

1	2	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
DQY	870.1250	☐ Class I ☒ Class II
Classification Panel: Cardiovascular		☐ Class III ☐ Unclassified

Indications *(from labeling)*

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be sed to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

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

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number: 2032493

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: MicroVention, Inc.	Establishment Registration Number: 2032493
Division Name *(if applicable)*	Phone Number *(including area code)*: (949) 461-3314
Street Address: 75 Columbia, Suite A	FAX Number *(including area code)*: (949) 349-1360

City	State / Province	ZIP/Postal Code	Country
Aliso Viejo	CA	92656	USA

Contact Name	Contact Title	Contact E-mail Address
Florin Truuvert	Director, Regulatory Affairs	florint@microvention.com

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number: (b)(4)

☐ Manufacturer ☒ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*: ( )
Street Address	FAX Number *(including area code)*: ( )

City	State / Province	ZIP/Postal Code	Country

Contact Name	Contact Title	Contact E-mail Address

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	ISO 10555-1	International Organization for Standardization	Sterile, Single-Use Intravascular Catheters	1997	1997
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

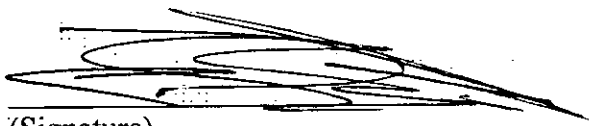
Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding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

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

Truthful and Accuracy Statement
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director, Regulatory Affairs of MicroVention, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Florin Truuvert
(Typed Name)

Aug 8, 2008
(Date)

510(k) Summary

Trade Name: Chaperon Guiding Catheter System

Generic Name: Percutaneous Catheter

Classification: Class II, 21 CFR 870.1250

Submitted By: MicroVention, Inc
75 Columbia
Aliso Viejo, California U.S.A.

Contact: Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K070970	Penumbra Inc., Neuron Intracranial Access System	Chaperon Guiding Catheter System	August 17, 2007

Device Description

The Chaperon Guiding Catheter system is designed to advance interventional and diagnostic devices through the vasculature. The device is intended for general intravascular use, including the neuro and peripheral vasculature. The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035 in or a 0.038 in guidewire or together with the Inner Catheter to access the desired anatomy.

Indication For Use

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

Verification and Test Summary Table

Bench Testing	Result
Surface Contamination & Tip Configuration	Met established criteria
Dimensional Inspection & Physical Attributes	Met established criteria
Tensile Strength	Met established criteria
Hub Attachment Strength	Met established criteria
Tip Attachment Strength	Met established criteria
Freedom from Leakage – Fluid & Air	Met established criteria
Leak Test (High Static Pressure)	Met established criteria
Hub Gauging	Met established criteria
Separation Force	Met established criteria
Stress Cracking	Met established criteria
Screwing Torque	Met established criteria
Ease of Assembly	Met established criteria
Resistance to Overriding	Met established criteria
Flow Rate	Met established criteria
Radio-Detectability	Met established criteria
Catheter Burst & Leakage	Met established criteria
Stiffness & Kink Resistance	Met established criteria
Durability & Lubricity & Fatigue	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Chaperon Guiding Catheter System compared with the predicate device Penumbra Neuron Intracranial Access System (K070970).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same processes.

In summary, the Chaperon Guiding Catheter System described in this submission is, in our opinion, substantially equivalent to the predicate device.

Indications for Use

510(k) Number (if known): _____

Device Name: Chaperon Guiding Catheter System

Indications for Use:

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

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

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]
ISO 10555-1: 1997/Amendment 1: 1999, Amendment 2: 2004 Sterile single-use intravascular catheter)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 16	
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 the standard? 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: Short-Term and Long-Term Intravascular Catheters Dated March 16, 1995.

[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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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

ECTION 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

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.

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.)

Form Approved: OMB No. 0910-0616
Expiration Date: 06-30-2008
See OMB Statement on Reverse

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER

Florin Truuvert

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

08/08/2008

3. ADDRESS (*Number, Street, State, and Zip Code*)

MicroVention, Inc.
75 Columbia, Suite A
Aliso Viejo, CA 92656

4. TELEPHONE AND FAX NUMBER (*Include Area Code*)

(T) +1 (949) 951-0516
(F) +1 (949) 349-1360

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*)

Chaperon Guiding Catheter System

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*)

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 # 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 #11
	Florin Truuvert Director, Regulatory Affairs
13. ADDRESS (*Number, Street, State, and Zip Code*) *(of person identified in #11 & 12)*	14. TELEPHONE AND FAX NUMBER (*Include Area Code*)
75 Columbia, Suite A Aliso Viejo, CA 92656	(T) +1 (949) 951-0516 (F) +1 (949) 349-1360

15. DATE OF CERTIFICATION 08/08/2008

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 applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

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.

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.

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 to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

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 at the time of submission 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, at the time the application/submission is being made, 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 # 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 NCT will be added automatically before number. Include any and all NCT numbers 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.

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 #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. & 15. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 12. Provide the date the certification is signed. This date may be different from the date provided in #2.

Executive Summary

The Chaperon Guiding Catheter system is designed to advance interventional and diagnostic devices through the vasculature. The device is intended for general intravascular use, including the neuro and peripheral vasculature. The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035 in or a 0.038 in guidewire or together with the Inner Catheter to access the desired anatomy.

Guiding Catheter - (b) (4)

(b) (4)

Inner Catheter - (b) (4)

(b) (4)

Device Name

The device trade names and common/classification names are:

Device Trade Name	Chaperon Guiding Catheter System
Device Generic Name	Percutaneous Catheter
Classification Name	Percutaneous Catheter
CFR Classification	21 CFR 870.1250
Device Class	Class II
FDA Panel	Cardiovascular Devices
Product Code	DQY

Address and Registration No.

The address and registration number of the manufacturer and sterilization sites for the Chaperon Guiding Catheter System are:

Manufacturer	MicroVention, Inc. 75 Columbia Aliso Viejo, California U.S.A
Establishment Registration No.	MicroVention 2032493
Contact	Florin Truuvert Director, Regulatory Affairs 75 Columbia Aliso Viejo, California U.S.A. Phone: (949) 461-3314 x 1147 Fax: (949) 349-1360
Sterilization Site	(b) (4) [redacted]

Device Class

Percutaneous Catheter is classified as Class II, DQY. The product has been designed, developed and tested using the FDA Special Controls Draft Guidance Document: Short-Term and Long-Term Intravascular Catheters Dated March 16, 1995.

Predicate Device Information

K070970, Penumbra Inc., Neuron Intracranial Access System

Labeling and Intended Use

Draft labels and Instructions For Use is provided in the Attachment 1.

Intended Use

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

The Indication statement can be found in the Attachment 1.

Device Description

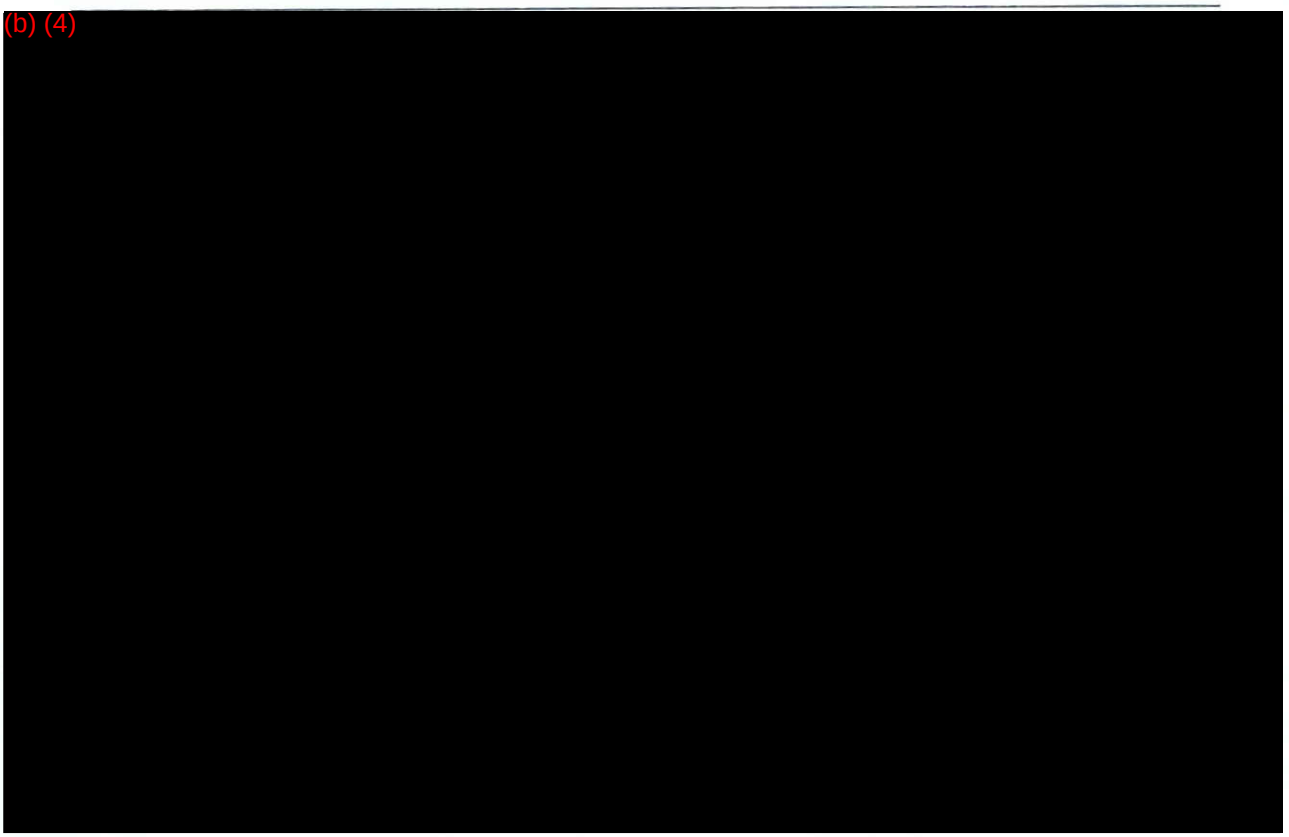
The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. The Chaperon Guiding Catheter system can be used individually with 0.035 in or a 0.038 in guidewire or together with the Inner Catheter to access the desired anatomy.

Guiding Catheter - (b) (4) [redacted]

Inner Catheter - (b) (4) [redacted]

Device Configurations and Dimensions

(b) (4)



(b) (4) Manufacturing Process

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(b) (4) Manufacturing Process

List of Attachments

1	Product Labels, Instructions For Use
2	Draft Product Drawings
3	(b)(4) Design and Development Quality Procedure
4	(b)(4) Risk Management Quality Procedure
5	(b) (4) Manufacturing Process
6	(b) (4) Manufacturing Process
7	(Biocompatibility Test Reports
8	MicroVention ISO Certificates

1	Product Labels, Instructions For Use
2	Draft Product Drawings
3	QP 4.1, Design and Development Quality Procedure
4	QP 4.9, Risk Management Quality Procedure
5	(b) (4) Manufacturing Process
6	(b) (4) Manufacturing Process
7	(b) (4) Manufacturing Process
8	MicroVention ISO Certificates

Chaperon™ Guiding Catheter 0.059 inch / 95 cm

6F MP1 JB2

REF GC695M1JB

Use By 2008-07

Chaperon™ Guiding Catheter

MICROVENTION® TERUMO

6F MP1 JB2 System

REF GC695M1JB Catalog Number

Guiding Catheter

95cm

MP1

ID 0.071 inch (1.8 mm)
6F (2.1mm)

Inner Catheter

117cm

JB2

ID 0.048 inch (1.2mm)
5F (1.7mm)

Hydrophilic Coating: 15 cm

maximum injection pressure 1000psi (6895kPa)

(01)00810170012426
(17)101200(10)080108
Chaperon 6F MP1 / JB2 REF GC695M1JB LOT 080108

(01)00810170012426
(17)101200(10)080108
Chaperon 6F MP1 / JB2 REF GC695M1JB LOT 080108

(01)00810170012426
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Chaperon 6F MP1 / JB2 REF GC695M1JB LOT 080108

CE 0297

MicroVention, Inc.
75A Columbia,
Aliso Viejo, CA 92656
PH: 949.461.3314
www.microvention.com
MADE IN JAPAN

EC REP MicroVention Europe
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

LOT 080108

Date of Manufacture 2008-01

Use By 2008-07

CONT Contents
1 Guiding Catheter
1 Inner Catheter

LB06006-M1JB MV-C6XXXXX

STERILE EO
Sterilized Using Ethylene Oxide

Rx-ONLY

LB06004 Rev. A 2008-04

Attention: Refer to Instructions For Use.

Do Not Reuse.

DRAFT
Chaperon™ Guiding Catheter
Instructions for Use (English)

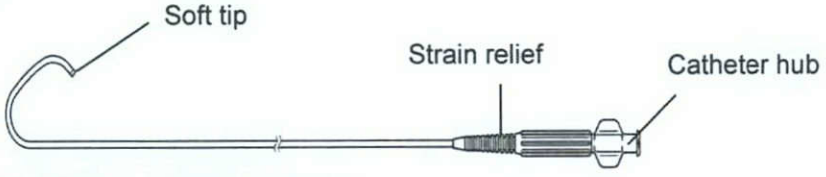
DEVICE DESCRIPTION

Chaperon Guiding Catheter consists of a Guiding Catheter and a Inner Catheter. The Guiding Catheter can be utilized individually with a guidewire or combined with the Inner Catheter to access the neuro and peripheral vasculature.

The Guiding catheter is designed to advance interventional and diagnostic devices through human vasculature. The Guiding catheter is reinforced by a stainless steel braiding, coated with a polytetrafluoroethylene (PTFE), and equipped with a strain relief and a catheter hub. The Guiding catheter has a preshaped distal segment to facilitate advancement of the Guiding Catheter and incorporates a radiopaque marker located approximately 5mm proximal to the distal tip.

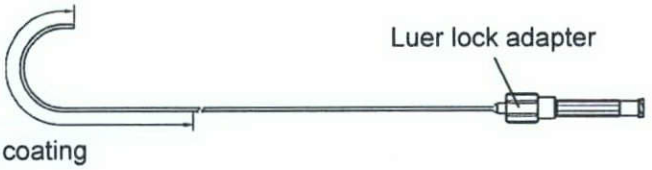
The Inner Catheter is designed to advance interventional and diagnostic devices through human vasculature. The Inner Catheter is reinforced by a stainless steel braiding, coated with a hydrophilic polymer in distal 15cm and equipped with a Luer lock adapter on the proximal end. The Inner Catheter has a preshaped distal segment to facilitate advancement of the Inner Catheter and a radiopacity in the distal segment. The Inner Catheter is compatible exclusively with the Guiding Catheter.

Guiding Catheter



Burst pressure of the catheter: 4.83MPa (700psi)

Inner Catheter



Burst pressure of the catheter: 8.27MPa (1200psi)

CONTENTS

One Guiding catheter or one Guiding catheter with an Inner catheter or one Inner catheter

INDICATIONS FOR USE

Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

Contraindic.

There are no known contraindications.

CAUTIONS

RX-Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNINGS

The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.

The device is provided sterile and non-pyrogenic unless the unit package is opened or damaged.

The device is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital and/or local government policy. Do not use if the packaging is breached or damaged.

Inspect the device prior to use for any irregularities or damage and discard if noted.

The device should be manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined. Do not use with Ethiodol or Lipiodol contrast media, or other such contrast media which includes the components of those agents.

PRECAUTIONS

Verify the device compatibility when using other ancillary devices commonly used in intravascular procedure. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.

Exercise care in handling the device to reduce the chance of accidental damage. Do not expose the device to organic solvents such as alcohol or medications, which might damage the device.

Potential complications include, but are not limited to: vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, death, and thrombus formation.

Extreme care must be taken to avoid damage to the vasculature through which the device passes. The device may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.

Torquing the device excessively while kinked may cause damage and result in separation of the device. Withdraw the entire system (the device, guidewire, and sheath introducer) if the device is kinked severely.

Take precaution when manipulating the device in tortuous vasculature to avoid damage to the device.

PREPARATION FOR USE

Gently remove the Guiding Catheter and the Inner Catheter (if applied) from its packaging. Inspect the devices to insure that there are not any damages. Do not use the devices that have been damaged in any way. If damage is detected, replace with other devices that are not damaged.

Hydrate the hydrophilic coating on the Inner Catheter (if applied) by soaking the whole inner catheter prior to introduce the Inner catheter into the Guiding Catheter.

Purge all of the lumens by flushing heparinized saline prior to use.

Introduce the Inner Catheter (if applied) into the Guiding Catheter thoroughly and lock the devices together tightly by the lock connectors. Do not use the catheters if extreme friction is detected.

DIRECTIONS FOR USE

Carefully insert the devices into the vasculature over the 0.035" or 0.038" guidewire through the introducer sheath.

Under fluoroscopic guidance, advance or withdraw the devices over the guidewire until the ideal position is obtained. If injection is necessary at this point, remove the guidewire and use the hub as an injection port.

Slowly remove the Inner catheter (if applied) leaving the Guiding catheter in the vessel.

Set up a continuous heparinized saline flush through the sidearm of a rotating hemostatic valve attached to the proximal hub of the device. It is recommended that continuous heparinized saline flush be maintained between the Guiding Catheter and any intraluminal device passed coaxially through it.

Any necessary adjustment should be made by physician using an interventional technique of choice.

STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the device under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

MATERIALS

The device does not contain latex or PVC materials.

SYMBOLS

LOT	Lot Number
REF	Catalog Number
CONT	Contents
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use by Date

MicroVention is a wholly owned subsidiary of Terumo Medical Corporation,

Date of Manufacture

Attention: Refer to Instructions For use

WARRANTY

MicroVention, Inc. warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Prices, specifications and model availability are subject to change without notice.

MicroVention, Inc.
75A Columbia
Aliso Viejo, CA 92656 USA
Tel: (949) 461-3314 Fax: (949) 461-3329
www.microvention.com

MicroVention is a wholly owned subsidiary of Terumo Medical Corporation,

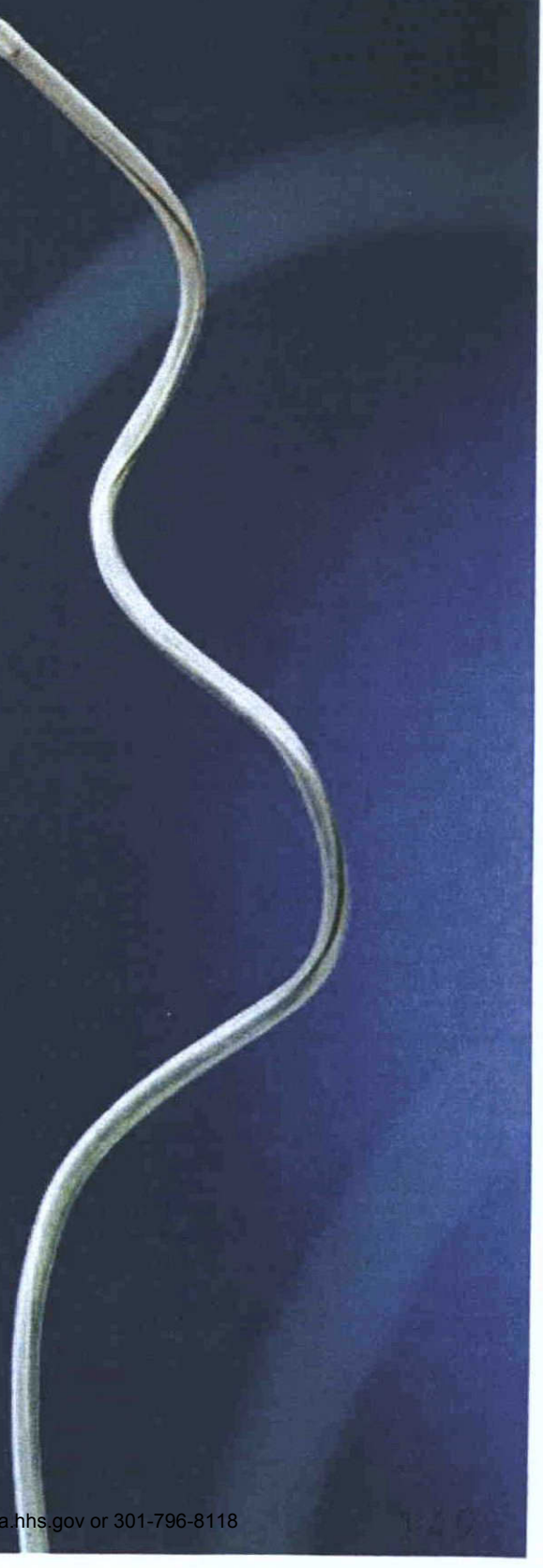
Support You Can Turn To

Neuron™ Intracranial Access System

Providing Improved Support, Closer to the Treatment Site

The Neuron Advantage

The Neuron Intracranial Access System features two innovative tools designed to work as a system to improve therapeutic access.



Penumbra

Designed with You in Mind

Neuron Delivery Catheter

Delivers therapeutic devices to the intracranial circulation

- Full-length coil reinforced shaft that tapers from a 6F proximal support zone, through a tapering transition zone, to a 5F distal flexible zone
- Distal flexible zone has a hydrophilic coating to further enhance access performance
- Higher placement in the neuro anatomy (than conventional guide catheters) provides more robust anatomical support due to enhanced catheter to vessel wall engagement

Neuron Select Catheter

- Helps place the Neuron Delivery Catheter in the chosen vessel location
- Hypotube proximal shaft combined with a braided polymer distal shaft with either an H1 or Simmons shaped tip

Ordering Information

Catalog Number	Description	Working Length	Distal Flexible Zone	Outer Diameter Proximal/Distal	Inner Diameter	Wire Compatibility
	Neuron Delivery Catheter:					
PND6F11512	6F Neuron Delivery Catheter, 115/12 Straight	115 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F11512M	6F Neuron Delivery Catheter, 115/12 MP	115 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F1156	6F Neuron Delivery Catheter, 115/6 Straight	115 cm	6 cm	6F / 5F	.053"	.035/.038"
PND6F1156M	6F Neuron Delivery Catheter, 115/6 MP	115 cm	6 cm	6F / 5F	.053"	.035/.038"
PND6F10512	6F Neuron Delivery Catheter, 105/12 Straight	105 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F10512M	6F Neuron Delivery Catheter, 105/12 MP	105 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F1056	6F Neuron Delivery Catheter, 105/6 Straight	105 cm	6 cm	6F / 5F	.053"	.035/.038"
PND6F1056M	6F Neuron Delivery Catheter, 105/6 MP	105 cm	6 cm	6F / 5F	.053"	.035/.038"
	Neuron Select Catheter:					
PNS35F137H1	3.5F Neuron Select Catheter, 137 H1	137 cm	42 cm	3.5F / 3.5F	.022"	.018"
PNS35F137SIM	3.5F Neuron Select Catheter, 137 SIM	137 cm	42 cm	3.5F / 3.5F	.022"	.018"

Penumbra

the path is clear

Penumbra, Inc. USA
1351 Harbor Street, Suite 201
San Leandro, CA 94577
T (510) 748-3200
F (510) 748-3201
www.penumbrainc.com

1265, Rev. C

Penumbra

THE NEURON™ INTRACRANIAL ACCESS SYSTEM

Providing Improved Support, Closer to the Treatment Site

The Neuron Intracranial Access System features two innovative tools designed to work as a system to improve therapeutic access.

Neuron Delivery Catheter

- Delivers therapeutic devices to the intracranial anatomy
- Full length coil reinforced shaft that tapers from a 6F support proximal zone, through a tapering transition zone, to a 5F distal flexible zone
- Distal flexible zone has a hydrophilic coating to further enhance access performance
- Higher placement in the neuroanatomy provides robust anatomical support due to enhanced catheter to vessel wall engagement
- The Neuron Delivery Catheter is available in eight configurations to help optimize support for a variety of anatomic and therapeutic clinical scenarios.

Neuron Select Catheter

- Helps place the Neuron Delivery Catheter in the chosen vessel location
- Hypotube proximal shaft combined with a braided polymer distal shaft with either an H1 or Simmons shaped tip
- The Neuron Select Catheter is available pre-shaped in either H1 or Simmons curves, to help facilitate selecting and delivering the Neuron Delivery Catheter to the anatomical location of choice.

Neuron Literature

Download Product Brochure
Download Neuron Instructions For Use

INSTRUCTIONS FOR USE

Penumbra

NEURON™ Intracranial Access System

English

DEVICE DESCRIPTION

Neuron Intracranial Access System is a two-catheter system comprised of the Neuron Delivery Catheter and the Neuron Select Catheter. The Neuron Delivery Catheter can be used individually with a 0.038in guidewire or together with the Neuron Select Catheter to access the desired anatomy.

Neuron Delivery Catheter:

The Neuron Delivery Catheter is a single lumen, coil-reinforced, variable stiffness catheter with a radiopaque markerband on the distal end and a Luer hub on the proximal end. The Neuron Delivery Catheter dimensions are included on the individual device label. The Neuron Delivery Catheter is compatible with introducer sheaths having an inner diameter of 6F or greater.

Neuron Select Catheter:

The Neuron Select Catheter is a single lumen, hypo-tube and braid-reinforced, variable stiffness catheter with a radiopaque markerband on the distal end and a Luer hub on the proximal end. The Neuron Select Catheter is available in three tip shapes (straight, Simmons, and H1). The Neuron Select Catheter tip shape and dimensions are included on the individual device label. The Neuron Select Catheter is compatible with the Neuron Delivery Catheter.

INDICATION FOR USE

The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Neuron Intracranial Access System should only be used by physicians who have received appropriate training in interventional techniques.

PRECAUTIONS

- The device is intended for single use only. Do not resterilize or reuse.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Use prior to the "Use By" date.
- Use the Neuron Intracranial Access System in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the Neuron Intracranial Access System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Moving or torquing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of an appropriate flush solution.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- acute occlusion
- air embolism
- death
- distal embolization
- emboli
- false aneurysm formation
- hematoma or hemorrhage at puncture site
- infection
- intracranial hemorrhage
- ischemia
- neurological deficits including stroke
- vessel spasm, thrombosis, dissection, or perforation

DEVICE PREPARATION AND USE

1. Select an appropriate sized Neuron Delivery Catheter based on the anatomy and length.
2. If used, select appropriate Neuron Select Catheter shape based on the target artery off the aortic arch.
3. Gently remove the Neuron Delivery Catheter and packaging card from the pouch by grasping the Neuron Delivery Catheter hub and packaging card and slowly pulling them out of the pouch.
4. Remove the Neuron Delivery Catheter from the packaging card by removing the hub from the card tabs before gently removing the Neuron Delivery Catheter shaft from the card tabs.
5. Remove the Rotating Hemostasis Valve (RHV) from the card tabs.
6. Inspect the Neuron Delivery Catheter for kinks or other damage. If any damage is observed, discard the Neuron Delivery Catheter.
7. Connect a rotating hemostasis valve to the hub of the Neuron Delivery Catheter. Flush the lumen with heparinized saline.
8. If used, insert the Neuron Select Catheter into the Neuron Delivery Catheter, and advance the Neuron Select Catheter until the distal tip of the Neuron Select Catheter is at the distal tip of the Neuron Delivery Catheter.

Select Catheter is at the distal tip of the Neuron Delivery Catheter.

9. If a 0.038in guidewire is used instead of the Neuron Select Catheter, insert the 0.038in wire into the Neuron Delivery Catheter, and advance the guidewire until the distal tip of the wire is at the distal tip of the Neuron Delivery Catheter.
10. Place an introducer sheath with minimum 6F inner diameter in the primary access artery.
11. Advance the Neuron Delivery Catheter and Neuron Select Catheter or 0.038in guidewire simultaneously into the introducer sheath, then extend the Neuron Select Catheter or 0.038in wire 5cm to 6cm distal to the tip of the Neuron Delivery Catheter.
12. If desired, a 0.018in guidewire may be introduced through the Neuron Select Catheter.
13. Advance the Neuron Intracranial Access System to the aortic arch, and then select the appropriate vessel with the Neuron Select Catheter or 0.038in guidewire.
14. After gaining access to the desired vessel with the Neuron Select Catheter or 0.038in guidewire, advance the Neuron Delivery Catheter over the Neuron Select Catheter or 0.038in wire into the desired vessel.
15. If used, remove the Neuron Select Catheter, and replace with an 0.038in or smaller guidewire.
16. Advance the Delivery Catheter and guidewire to the vascular site and remove the guidewire.

SYMBOLS GLOSSARY

⚠	Attention, see instructions for use		
Rx Only	Prescription only – US Federal Law restricts this device to use by or on the order of a physician		
NONPYROGENIC	Nonpyrogenic		
STERILE EO	Sterile (ethylene oxide)		
ON OFF	Aspiration Flow ON / Aspiration Flow OFF		
LOT	Lot number	⊘	Do not reuse
⧗	Use by	REF	Catalogue number

Manufacturer
Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502 USA
Tel: 510-748-3200 • Fax: 510-748-3232

Penumbra

CE 0050

EU Representative
MedPass International Ltd.
Windsor House, Barnett Way
Barnwood, Gloucester GL4 3RT UK

1125, Rev C

WARRANTY

Penumbra Inc. (Penumbra) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Penumbra's control directly affect the device and the results obtained from its use. Penumbra's obligation under this warranty is limited to the repair or replacement of this device and Penumbra shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Penumbra neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Penumbra assumes no liability with respect to devices reused, reprocessed, or resterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such device.

Design Drawing of Chaperon

Update 080515

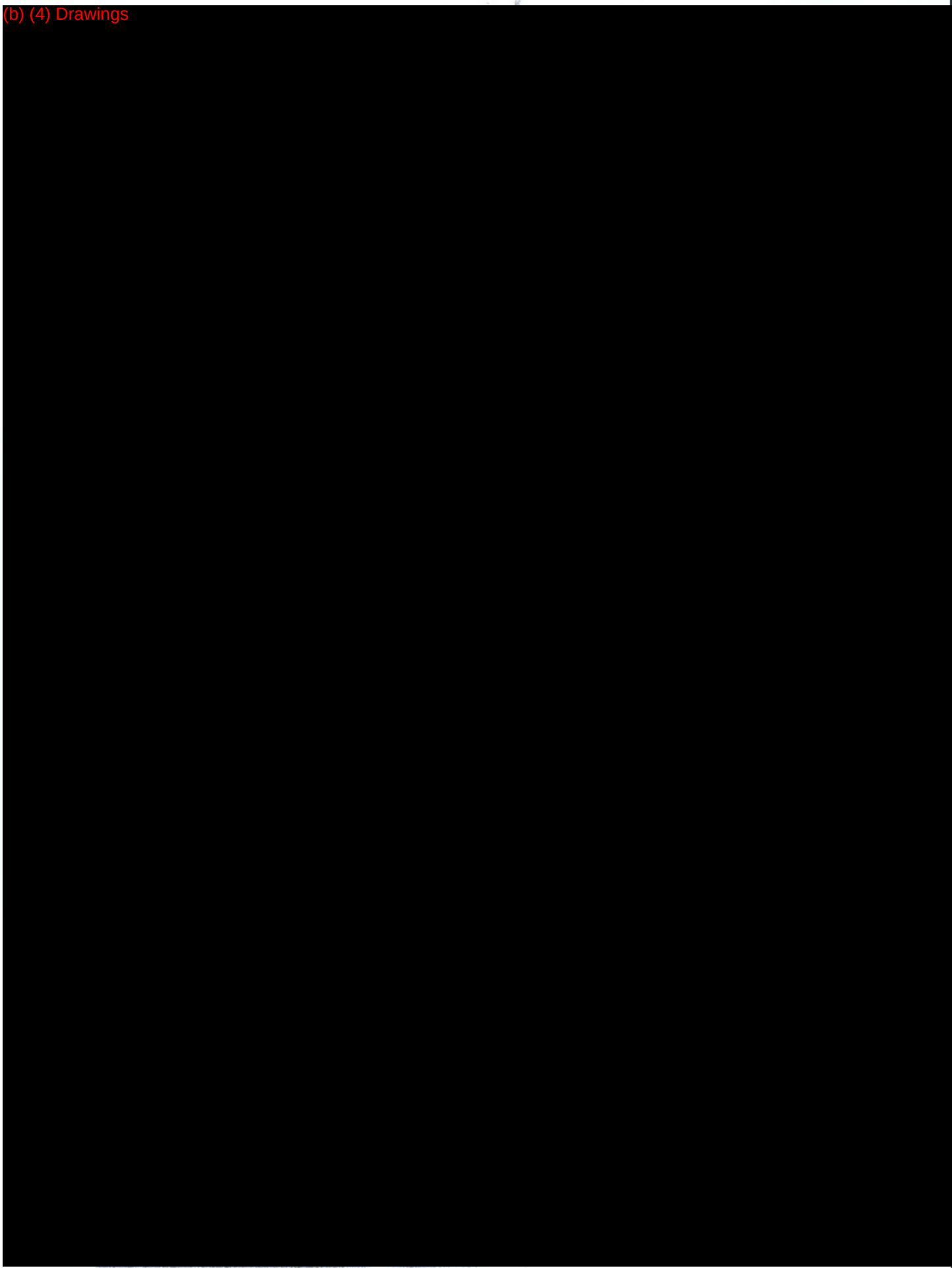
Chaperon (Guiding Catheter)

(b) (4) Drawings

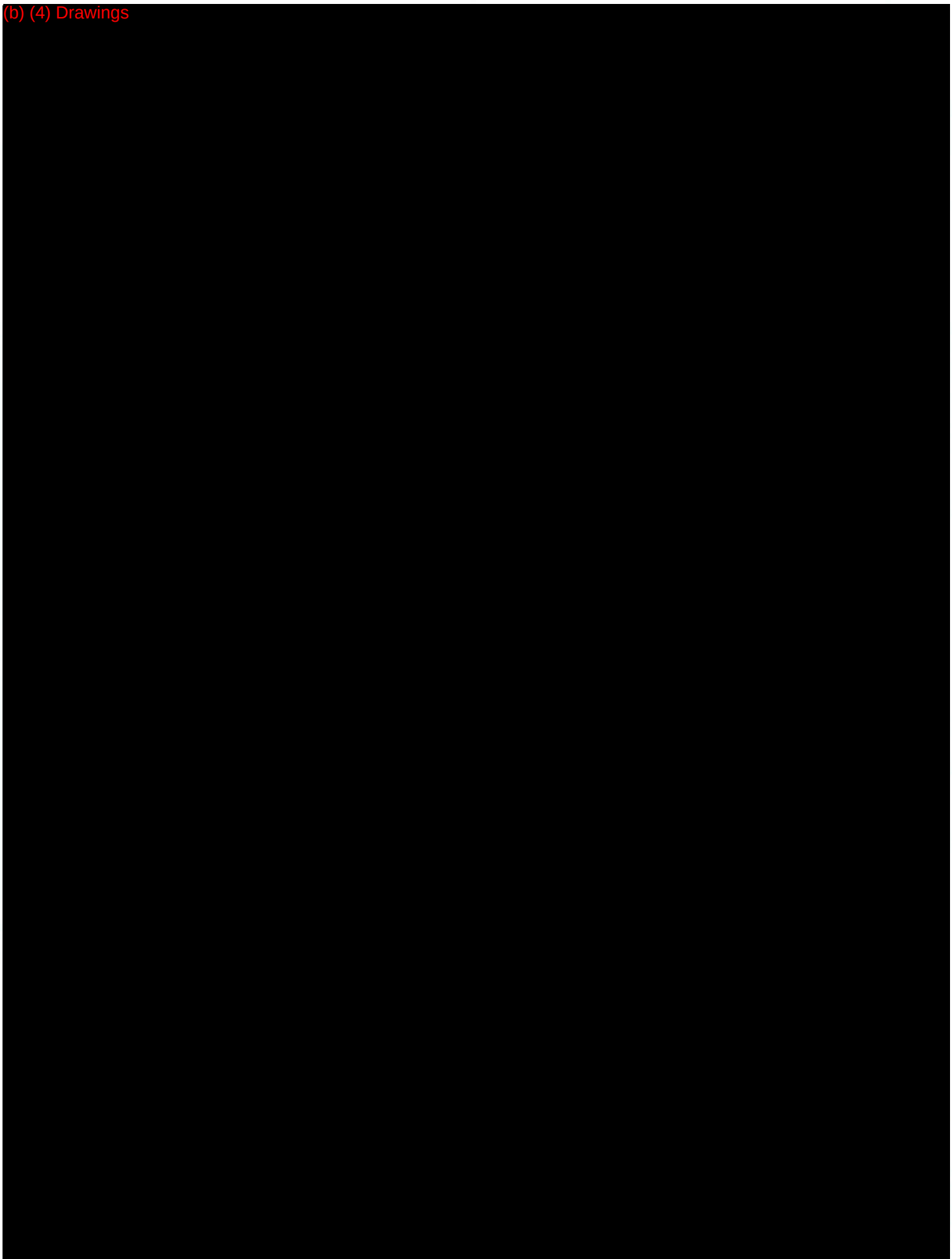
Update 080515

Chaperon (Inner Catheter)

(b) (4) Drawings



(b) (4) Drawings



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(b) (4) Proprietary Information

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			
3. Does this device type require a PMA by regulation? (Please see management.)			
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			
5. a. Did the firm request expedited review? (See management,)			
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			

Rev. 5/30/07

Department of Health and Human Services **Memorandum**

Food & Drug Administration
Center of Device & Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Date: December 6, 2008
From: Kenneth J. Cavanaugh, Jr., Ph.D., Acting Chief
FDA/CDRH/ODE/DCD/PVDB

Subject: Third-party review of K082385 / S002

Device Name:	Chaperon Guiding Catheter
Product Code:	DQY
Regulation:	21 CFR 870.1250 (Class II)
Manufacturer:	MicroVention, Inc.
Contact:	Mark Job Reviewer Regulatory Technical Services 1394 25th Street NW Buffalo, MN 55313 Phone: (763) 682-4139 Fax: (763) 682-4420

Background:
MicroVention, Inc. has submitted a traditional 510(k) via the third-party program for the Chaperon Guiding Catheter, which would be a Class II device upon clearance. The proposed device and product code are eligible for third-party review. The proposed predicate is the Penumbra Neuron Intracranial Access System (K070970).

The manufacturer received requests for additional information on 9/9/08 and 10/6/08. In the current submission, the manufacturer has attempted to respond to FDA's concerns.

Comments:
The outstanding deficiency identified by FDA in response to K082385/S1 is presented below, followed by a summary and review of the sponsor's response.

(b)(4)

[redacted]

(b)(4) [redacted]

The manufacturer provided the results of an acute animal study involving the use of the device in porcine carotid arteries. Study endpoints included histopathology of the target vessels and qualitative evaluation of performance characteristics as compared to a predicate device.

Because this testing was requested in response to the proposed neurovascular indication, a consulting review was requested from Ms. Tajanay Ki, DGRND/PRSB. Ms. Ki's review memorandum is attached. I concur with Ms. Ki's conclusion that the results suggest substantially equivalent performance.

Recommendation: Substantial Equivalence (SE)

12/9/08

510(K) CONSULT REVIEW MEMORANDUM

TO: Ken Cavanaugh, PhD (ODE/DCD/PVDB)

FROM: Tajanay Ki, (ODE/DGRND/PRSB)

DATE: December 5, 2008

SUBJ: K082385 / S002 – Neuro Consult
Chaperon Guiding Catheter
Microvention, Inc.

CONTACT: Mark Job, Responsible Third Party Official; Regulatory Technology Services, LLC; 763-682-4139-telephone; mark@markjob.com

RECOMMENDATION: Substantially Equivalent

SUMMARY:

The Chaperon Guiding Catheter contains an indication for neurological usage and I was asked to evaluate the neurological indication. In the original 510(k) review, I recommended that animal testing be conducted along with particulate testing. In S1, the sponsor conducted the particulate testing and provided additional information on the silicon flow model used for the bench testing. They did not conduct the requested animal testing. I again recommended that animal testing be completed in order to assess the neurological indication. Now, in S2, the sponsor has conducted animal testing using a swine model. I recommend that the testing is adequate and that the device is substantially equivalent to the predicate device in terms of the neurological indication.

BACKGROUND INFO:

Intended Use

The Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.

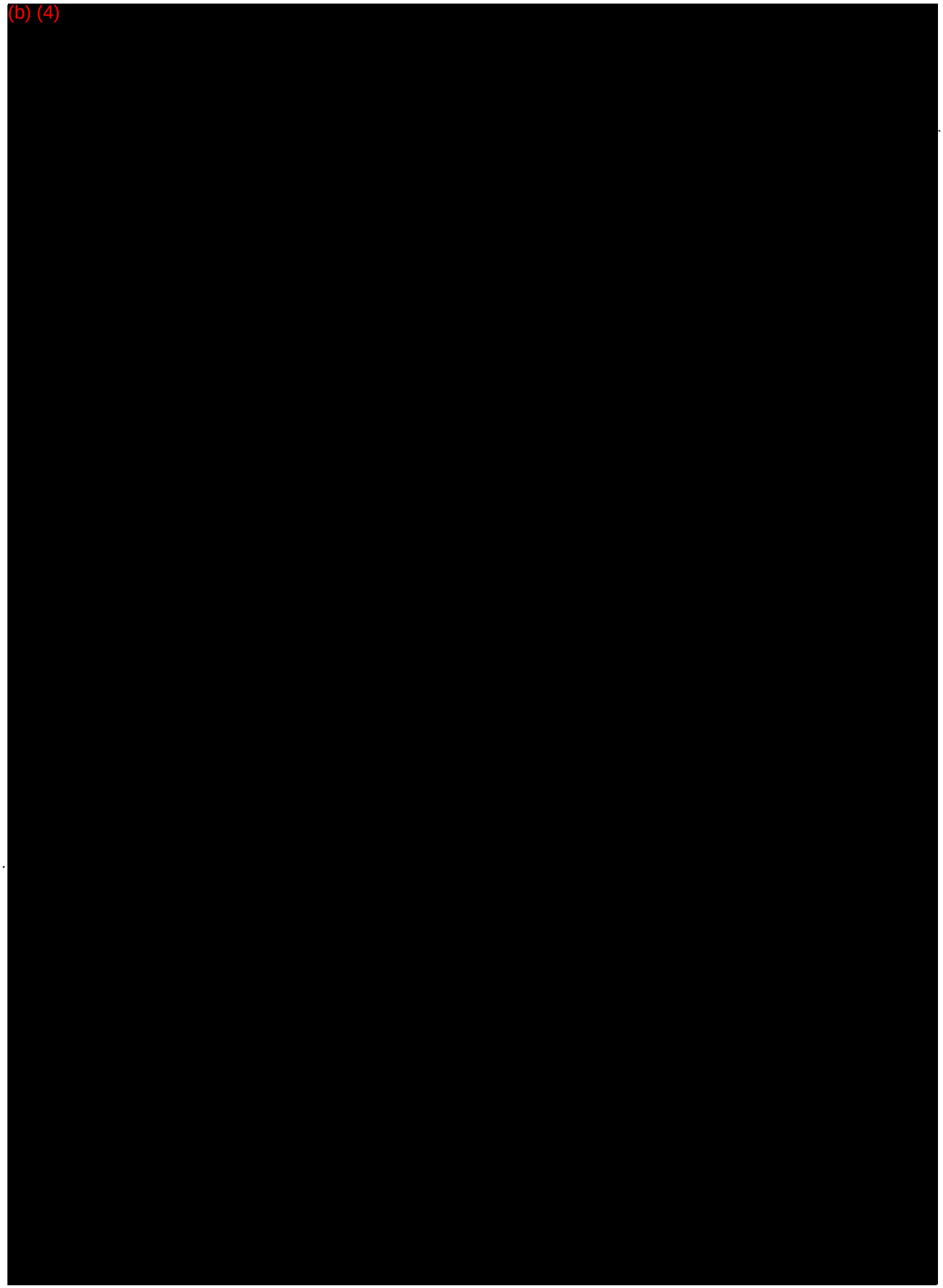
Device Description

The Chaperon Guiding Catheter is a two-catheter system comprised of an outer catheter and an inner catheter. Both catheters are single-lumen catheters reinforced by stainless steel braiding, and have pre-shaped distal tips to facilitate advancement. The tips are available in a variety of configurations. The inner catheter possesses a hydrophilic coating on the distal segment to increase lubricity.

REVIEW OF ANIMAL DATA TESTING:

(b) (4) [redacted]

(b) (4)



(b) (4)

COVER SHEET MEMORANDUM

From: Reviewer Name Kaa Cavanaugh

Subject: 510(k) Number K082385

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/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☐ 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://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			✓
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/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.)		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
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 870.1250 **Class*** II **Product Code** DQY

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) PVD3 (Branch Code) 12/9/08 (Date)

Final Review: (Division Director) 12/8/08 (Date)

Rev. 5/30/07

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kay Cavanagh

Subject: 510(k) Number K082385/S1

To: The Record

Please list CTS decision code A1

☐ 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 _____, 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.)			
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.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
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: _____

(Branch Chief) (Branch Code) (Date)

Final Review: _____

(Division Director) (Date)

Department of Health and Human Services **Memorandum**

Food & Drug Administration
Center of Device & Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Date: October 6, 2008
From: Kenneth J. Cavanaugh, Jr., Ph.D., Acting Chief
FDA/CDRH/ODE/DCD/PVDB

KJC 10/6/08

Subject: Third-party review of K082385 / S001

Device Name:	Chaperon Guiding Catheter
Product Code:	DQY
Regulation:	21 CFR 870.1250 (Class II)
Manufacturer:	MicroVention, Inc.
Contact:	Mark Job Reviewer Regulatory Technical Services 1394 25th Street NW Buffalo, MN 55313 Phone: (763) 682-4139 Fax: (763) 682-4420

Background:
MicroVention, Inc. has submitted a traditional 510(k) via the third-party program for the Chaperon Guiding Catheter, which would be a Class II device upon clearance. The proposed device and product code are eligible for third-party review. The proposed predicate is the Penumbra Neuron Intracranial Access System (K070970).

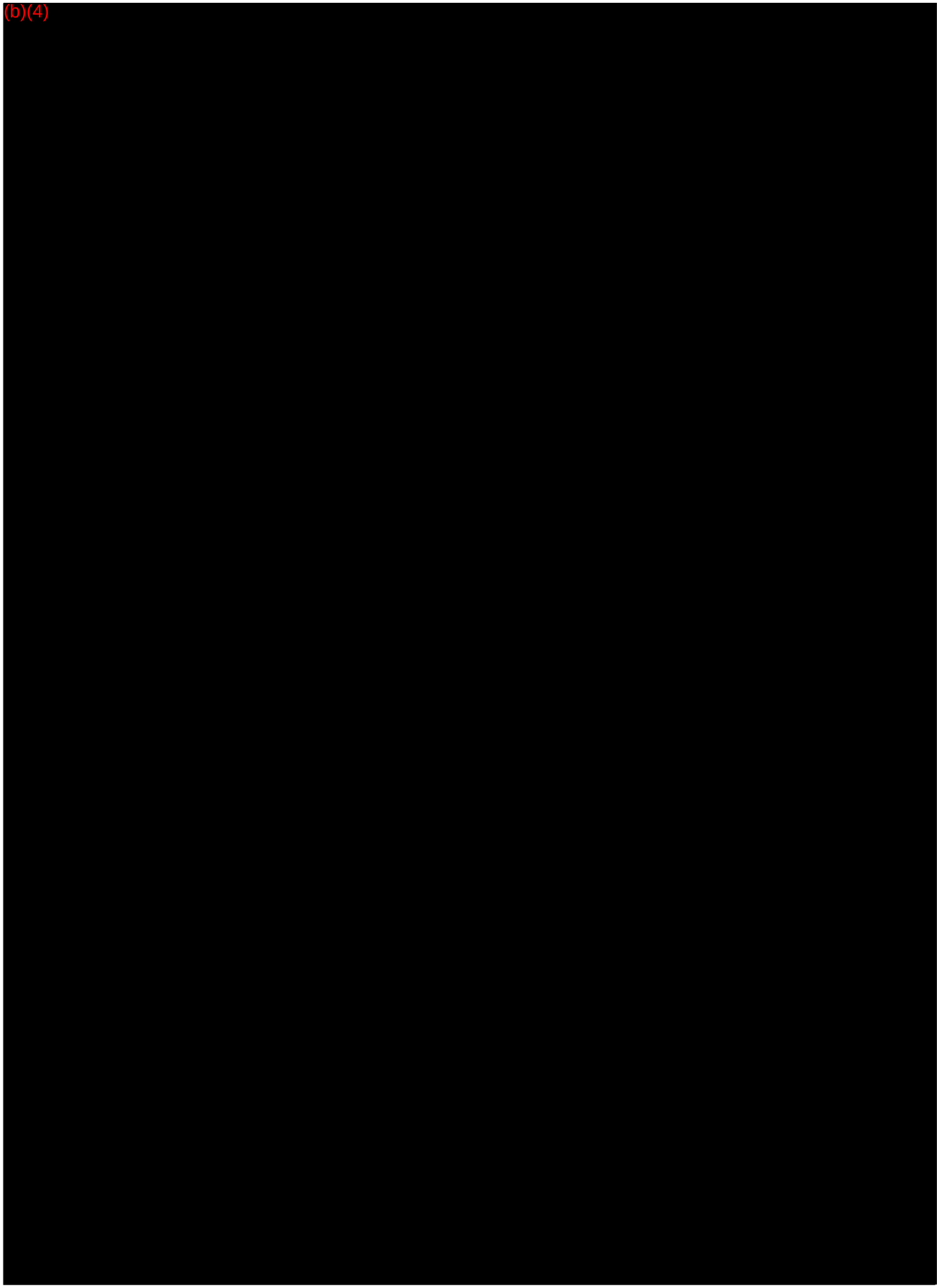
The manufacturer received a request for additional information on 9/9/08. In the current submission, the manufacturer has attempted to respond to FDA's concerns.

Comments:
Each of the deficiencies originally identified by FDA is presented below, followed by a summary and review of the sponsor's response.

(b)(4)

[redacted]

(b)(4)



Cavanaugh, Kenneth J

From: Ki, Tajanay R
Sent: Thursday, October 02, 2008 5:14 PM
To: Cavanaugh, Kenneth J
Subject: RE: Indications Statement

Hi Ken:

I discussed the need for animal data for the neurovascular indication with Peter and Ryan (neurosurgeon) and they still believe that animal data is necessary. I've drafted a deficiency below:

(b)(4)

[redacted]

Please let me know if you need any other information.

Thanks,
Tajanay

Tajanay Ki, Biomedical Engineer
Plastic and Reconstructive Surgery Devices Branch
U.S. Food and Drug Administration
9200 Corporate Blvd, HFZ-410
Rockville, MD 20850
(240) 276-3625 (voice)
(240) 276-3733 (fax)
tajanay.ki@fda.hhs.gov

From: Cavanaugh, Kenneth J
Sent: Monday, September 29, 2008 10:44 AM
To: Ki, Tajanay R
Subject: RE: Indications Statement

Sure:

"The Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries."

Ken

From: Ki, Tajanay R
Sent: Monday, September 29, 2008 10:43 AM
To: Cavanaugh, Kenneth J
Subject: Indications Statement

Hi Ken:

Can you forward me the indications statement for the guiding catheter?

Thanks,
Tajanay

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kay Cavanaugh

Subject: 510(k) Number K082385

To: The Record

Please list CTS decision code A1

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☑ 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://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/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.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
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: _____ PUPB 9/8/08
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Rev. 5/30/07

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			✓
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			✓
3. Does this device type require a PMA by regulation? (Please see management.)			✓
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			✓
5. a. Did the firm request expedited review? (See management.)			✓
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		✓
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		✓
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		✓	

Rev. 5/30/07

Department of Health and Human Services **Memorandum**

Food & Drug Administration
Center of Device & Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Date: September 8, 2008
From: Kenneth J. Cavanaugh, Jr., Ph.D., Acting Chief
FDA/CDRH/ODE/DCD/PVDB

Subject: Third-party review of K082385

Device Name:	Chaperon Guiding Catheter
Product Code:	DQY
Regulation:	21 CFR 870.1250 (Class II)
Manufacturer:	MicroVention, Inc.
Contact:	Mark Job Reviewer Regulatory Technical Services 1394 25th Street NW Buffalo, MN 55313 Phone: (763) 682-4139 Fax: (763) 682-4420

Background:
MicroVention, Inc. has submitted a traditional 510(k) via the third-party program for the Chaperon Guiding Catheter, which would be a Class II device upon clearance. The proposed device and product code are eligible for third-party review. The proposed predicate is the Penumbra Neuron Intracranial Access System (K070970).

The Chaperon Guiding Catheter is a two-catheter system comprised of an outer catheter and an inner catheter. Both catheters are single-lumen catheters reinforced by stainless steel braiding, and have pre-shaped distal tips to facilitate advancement. The tips are available in a variety of configurations. The inner catheter possesses a hydrophilic coating on the distal segment to increase lubricity.

The proposed indications for use are: "The Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries." The submission includes all the required elements for traditional, third-party 510(k) submissions, including a 510(k) summary and indications for use form.

The third-party reviewer has recommended a Substantial Equivalence (SE) determination for this 510(k). My comments on this review are provided below.

Comments:
The types of biocompatibility and *in vitro* tests conducted on the subject device appear to be appropriate for this device type and are consistent with the testing conducted on the predicate. The results do not raise any concerns.

Because the indications include use in the neurovasculature, I discussed the suitability of the testing with Tajanay Ki, PRSB reviewer, who is familiar with neurovascular catheters and who provided a consulting review for the predicate device. Ms. Ki stated that animal study data would typically be needed to support clearance for neurovascular catheter-based devices such as this, based on the tortuosity and fragility of these vessels. Such a study was not reported in the submission.

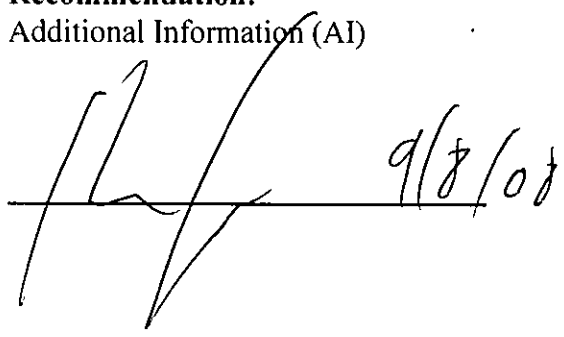
Additionally, Ms. Ki believed that particulate generation testing should be conducted for the neurovascular indication. While the sponsor did evaluate the function and durability of the hydrophilic coating of the inner catheter component after application of bending loads (which would generally be acceptable for peripheral indications), Ms. Ki believes that a more rigorous assessment was indicated, given the criticality of the end organ and the fact that particulate generation could results from device areas other than the coating.

Based on these findings, the sponsor should address the following deficiencies.

(b)(4)

[redacted]

Recommendation:
Additional Information (AI)



THIRD PARTY REVIEW CHECKLIST

1. Is this 510(k) eligible for third party review, i.e.:		
a. Is the device on the list of eligible devices?*	(Yes)	No
b. Can a determination of substantial equivalence be made without clinical data?	(Yes)	No
c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation?	Yes	(No)

IF THE ANSWER IS "NO" TO A or B above, or "YES" to C above, PLEASE BRING THE SUBMISSION TO POS IMMEDIATELY.

Are the following elements included in the submission:

2. A cover letter signed by the third party's official correspondent clearly identifying:		
a. The purpose of the submission	(Yes)	No
b. The name and address of the third party	(Yes)	No
c. The name and address of the 510(k) holder	(Yes)	No
d. The name of the device (trade name, common or usual name, and FDA classification name)	(Yes)	No
e. The third party's recommendation with respect to the substantial equivalence of the device	(Yes)	No
f. The date the third party first received the 510(k) from the 510(k) holder	(Yes)	No

3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	(Yes)	No

4. The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	(Yes)	No

5. A complete review of the 510(k), signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device.	Yes	No

6. A certification that:		
a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	Yes	No
b. Statements made in the third party's review are true and accurate to the best knowledge of the third party	Yes	No
c. The third party's review is based on the 510(k) that it is submitting with the review	Yes	No
d. The third party understands that the submission to the government of false information is prohibited	Yes	No

7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications:		
a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)	Yes	No
b. Record of Deficiencies, if applicable (attachment 1a)	Yes	No
c. Indications for Use Form	Yes	No
d. 510(k) Summary or Statement (attachment 1c)	Yes	No
e. 510(k) Truthful and Accurate Statement (attachment 1d)	Yes	No
f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (attachment 2)	Yes	No

IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.

COMMENTS: _____

_____

_____

*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring to POS.

 K082385/52

Date: November 11, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

K-35

RE: Additional Information for K082385
Microvention, Inc. Chaperon Guiding Catheter

To Whom It May Concern:

Enclosed in duplicate is the following information:

As requested by Dr. Kenneth Cavanaugh the following document is the response to the request for additional information dated October 6, 2008. The additional information supplied by the manufacturer includes the requested animal test data complete with the histology analysis. The CD included include the same information as the printed. This will provide you with the color photos of the histology. The following page addresses the items raised. The information addresses the questions raised but does not require a change to the review memo, thus a decision of substantially equivalence is recommended.

If you should have any further questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

(b) (4) Test Data

(b) (4) Test Data

(b) (4) Test Data

(b) (4) Test Data

(b) (4) Test Data

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

September 23, 2008

MICROVENTION, INC.
c/o REGULATORY TECHNOLOGY SERVICES,
1394 25TH STREET, NW
BUFFALO, MN 55313
ATTN: MARK JOB

510(k) Number: K082385
Product: CHAPERON GUIDING CATHETER

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html. 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/cdrh/ode/guidance/1567.html. 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.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K082385/S1

Date: September 22, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC

SEP 23 2008

Received

RE: Additional Information for K082385
Microvention, Inc. Chaperon Guiding Catheter

To Whom It May Concern:

Enclosed in duplicate is the following information:

As requested by Dr. Kenneth Cavanaugh the following document is the response to the request for additional information dated September 8, 2008. The additional information supplied by the manufacturer has been reviewed and found to answer all of the questions raised in the email. The following page addresses the items raised. The information addresses the questions raised but does not require a change to the review memo, thus a decision of substantially equivalence is recommended.

If you should have any further questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

K[illegible]

MICROVENTION®
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ingenuity. for life.

September 21, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850
Attn: Kenneth Cavanaugh, Ph.D.

RE: Response to Request for Additional Information
510(k) No. K082385 (Chaperon Guiding Catheter System)

Dear Dr. Cavanaugh,

This letter is in response to your request for additional information by letter dated Sep 9, 2008, and during our telephone conference of Thursday, September 11, 2008, with respect to the above-referenced 510(k).

Please find attached a copy of each of the items in the FDA letter, along with the company's written response.

Respectfully,

Florin Truuvert, RAC
Director, Regulatory Affairs
florint@microvention.com

FDA Item 1.

FDA recognizes that you have conducted extensive bench testing on your device. Given the tortuosity and potential for injury associated with the neurovasculature, FDA believes that evaluation of device performance using an animal model is essential to understanding the substantial equivalence of your device as compared to other guide catheters indicated for neurovascular use. Please conduct in-vivo evaluation of your device using animal neurovascular model so that FDA can better determine the risk posed by device use for this indication. Your study should include semi-quantitative evaluation of the ability of your device to access various locations in the neuroanatomy, the frictional effects within neurovascular tissues and radiopacity in an animal model.

MicroVention Response:

MicroVention tested total of 20 Chaperon samples of various tip configurations, subjecting the device to worst-case anticipated clinical settings according to the written test protocol TP08-098. Samples were selected based on the worse case for simulated use with smallest tip angle representing the most challenging angle for friction during advancement and retraction.

All samples met the established acceptance criterion of = 5 establishing the 95%/95% confidence/reliability level. Both test protocol and report TP/TR 08-098 were provided in the original 510(k) K082385 submitted on August 8, 2008.

We believe that the bench top tests support the effectiveness of the device. To that point, we provide below, additional details on the bench top test model that was used to assess the overall catheter performance including device compatibility, guidewire insertion/removal, microcatheter insertion/removal, advancement and retraction/removal.

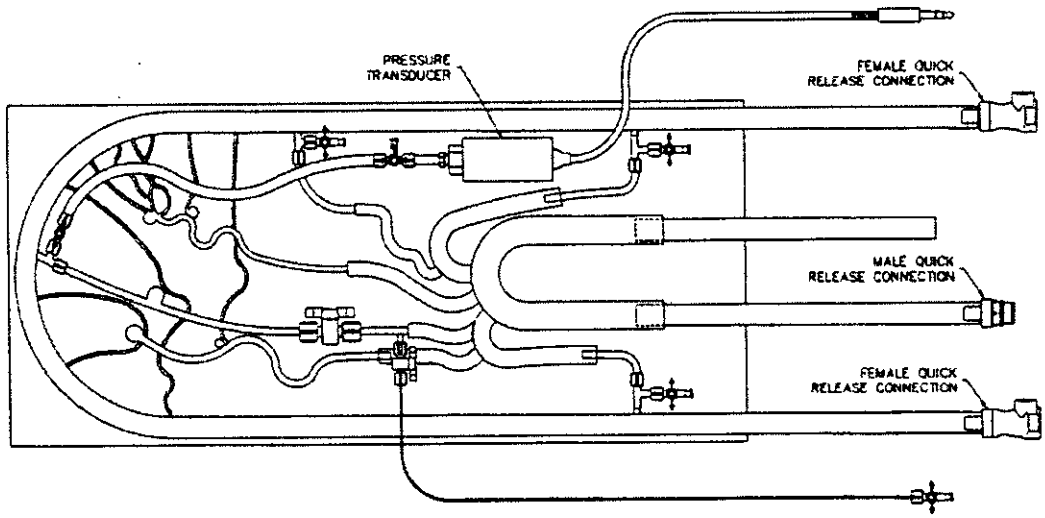
We highlight this information to explain the rigorous test methodology applied to these devices. As reported in the attached publication, the controlled experiments was designed to evaluate the performance of catheter systems and compare load forces required to propel state-of-the-art, hydrophilically coated catheters from each of four manufacturers through a standardized tortuous pathway. As concluded in the report, all reinforced catheters tested established good and reproducible performance when tested in the model.

In Chaperon case, the *in-vitro* catheter trackability included a referenced tortuousity model to simulate the three-dimensional pathway of the intracranial carotid circulation.[1] The results from this experiment showed that the Chaperon catheters were reliable at a 95%/95% confidence/reliability level. MicroVention believes that this model - combined with the additional mechanical test data submitted - simulates the clinical environment appropriately, and allows measurement of acceptable performance.

***In-Vitro* "Simulated Use" Test in Simulated Intra-Cranial Silicon Aneurysms**

[1] Zoarski, Mathis, & Hebel (1998) Performance Characteristics of Microcatheter Systems in a Standardized Tortuous Pathway. *Am* J Neuroradiol 19: 1571-1576.

The test simulates a neurointerventional embolization procedure using 37°C fluid, guide catheter, microcatheter and guidewire.



We believe our in vitro tests of simulated use appropriately model the clinical environment better than available acute, animal models. For example, the accepted, laboratory animal aneurysm models - swine vein-pouch; canine vein-pouch; rabbit elastase - all use the common carotid arteries as the test sites.[2]

This extra-cranial aneurysm location reduces the tortuousity experienced by the test devices. Therefore, our *in-vitro* simulation of the three-dimensional intra-cranial circulation is a better assessment of ease of delivery. In terms of acute complications, the animal models are known to test chronic implant material features: the swine vein-pouch model is most useful for stent implantation; the canine vein-pouch model is appropriate for coil recanalization assessment; and the rabbit elastase model has evolved into a biomechanical assay system. Thus, we carefully tested the mechanical attributes of the catheters such as delivery, (advancement, retraction/removal). We suggest that this well-known method of bench top test fully demonstrates, without an animal study, that this aspect of the Chaperon is free of acute complication risks such as catheter buckling, kinking, deformity or degradation. It is for this reason that MicroVention respectfully asks that this information be reviewed and considered as evidence of substantial equivalence to the predicate device and obviates the need for animal testing.

[2] Cloft et al. (1999) Endovascular Creation of an In Vivo Bifurcation Aneurysm Model in Rabbits. Radiol 213:223-228.

FDA Item 2.

FDA believes that catheter-based devices such as yours may generate particulate matter during use, which may result in serious adverse effects if used in the neurovasculature.
While FDA appreciates that you conducted an evaluation of the function of the hydrophilic coating of inner catheter after mechanical challenge, it is not clear that this assessment fully evaluated the risks of particulate generation. Please conduct an in vivo assessment of the potential for your device to generate clinically significant embolic material during simulated use. This assessment should be conducted after subjecting the device to worst-case anticipated clinical conditions (for example, by tracking through simulated tortuous neurovascular anatomy and collecting particulates generated during tracking).

MicroVention Response:

The "particulate matter in injection" was performed by PMT (Particle Measurement Technology Co.), an independent laboratory per USP XXX Section <788>. A total of 4 Chaperon Guiding Catheter System samples consist of two Guide Catheters and two Inner Catheters combined with two control samples were tested by automated light obscuration particle counter.

Per the FDA request, samples were tested in the simulated intra-cranial silicon aneurysms tortuous flow model. Samples were prepared according to the IFU. The Inner Catheter was introduced into the Guiding Catheter completely and both devices were secured together by rotating the luer lock adapter of the Inner Catheter onto the Guiding Catheter hub. The catheters were subjected to worst-case anticipated clinical conditions by cycling (advancement and retraction) ten times. The sample flushes collecting particulates generated during tracking were then tested according to the USP <788>.

As documented in the PMT Particle Analysis Report, the result meets the requirements of the particle test if the statistical particle count does not exceed 25 particles equal to or greater than 10 microns in size, and/or 3 particles equal to or greater than 25 microns in size.

A copy of the PMT Particle Analysis Report is provided in Attachment 2.

Sep 21, 2008

List of Attachments

Attachment 1	Zoarski, Mathis, & Hebel (1998) Performance Characteristics of Microcatheter Systems in a Standardized Tortuous Pathway. ***Am*** J Neuroradiol 19: 1571-1576. Cloft et al. (1999) Endovascular Creation of an In Vivo Bifurcation Aneurysm Model in Rabbits. Radio1 213:223-228
Attachment 2	PMT Particle Analysis Report

(b) (4) Proprietary Information

AJNR Am J Neuroradiol 19:1571–1576, September 1998

Performance Characteristics of Microcatheter Systems in a Standardized Tortuous Pathway

Gregg H. Zoarski, John M. Mathis, and J. Richard Hebel

BACKGOUND AND PURPOSE: Published reports of controlled experiments designed to evaluate the performance of over-the-wire microcatheter systems are rare and have often been based on subjective impressions from small clinical series. This investigation was designed to compare the load forces required to propel state-of-the-art, hydrophilically coated microcatheters from each of four manufacturers through a standardized tortuous pathway constructed of polytetrafluoroethylene tubing.

METHODS: Currently available hydrophilically coated microcatheters were provided by four manufacturers. A 20-cm long, three-dimensional pathway simulating the intracranial carotid circulation was constructed of 0.065-in. (inner diameter) polytetrafluoroethylene tubing and immersed in a water bath at 37°C. Testing was performed using an Instron tabletop load frame fitted with a 2-lb load cell. Durability and load force tests were conducted using a 0.014-in. stainless steel noncoated guidewire, with the wire tip protruding 1 cm beyond the catheter tip. At least four samples of microcatheters from each manufacturer were tested.

RESULTS: Extensive trackability testing of the guidewire alone established reproducible performance with maximum load forces of less than 8 g. Maximum gram forces for the four reinforced microcatheters were not greatly different, measuring between 9 and 14 g. Excessive buckling of the only nonreinforced catheter was initially overcome early in the pathway in a staccato, stepwise fashion. After reaching a critical load, however, the catheter and guidewire prolapsed.

CONCLUSION: All reinforced microcatheters tested established good and reproducible performance in our model. Reinforced microcatheters provided superior trackability over the one nonreinforced device tested.

Over-the-wire microcatheter systems are used in most intracranial neurointerventional vascular procedures. These catheters are produced by a number of manufacturers both within and outside the United States and incorporate a variety of design features. Demand from the neurointerventional community as well as competition in the marketplace have been the driving forces in the development of new and innovative products. Published reports of catheter performance are rare in the literature and most often are merely impressions derived from small clinical series (1–5). In vitro studies reporting the performance characteristics of microcatheters are even more uncommon (6, 7).

Failure to access the distal intracranial circulation with an over-the-wire microcatheter is most commonly encountered in a tortuous vascular system. The ease with which a microcatheter follows a guidewire through a tortuous system has been termed "trackability." Innovations in material technology, hydrophilic coating, and mechanical catheter design have, at least subjectively, greatly improved the trackability of microcatheter systems during the past several years.

Microcatheters may be broadly divided into reinforced and nonreinforced devices. Reinforced devices are supported by an integral coil or braid. Most manufacturers offer at least one model of microcatheter with hydrophilic coating. These hydrophilic coatings are of proprietary formulation and are thought to be more lubricious than noncoated microcatheters.

The purpose of this study was to compare the load forces required to propel hydrophilically coated microcatheters from each of four major manufacturers

Received September 11, 1997; accepted after revision March 10, 1998.

Presented at the annual meeting of the American Society of Neuroradiology, Toronto, Canada, May 1997.

From the Departments of Radiology (G.H.Z.) and Epidemiology (J.R.H.), University of Maryland Medical Center, and the Division of Neuroradiology (J.M.M.), The Johns Hopkins Hospital, Baltimore, MD.

Address reprint requests to Gregg H. Zoarski, MD, Department of Radiology, University of Maryland Medical Center, 22 S Greene St, Baltimore, MD 21201.

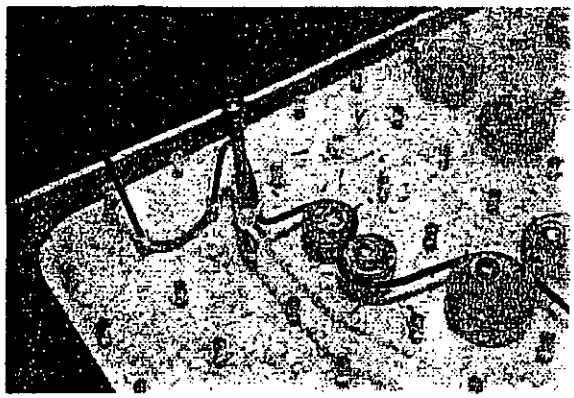


Fig 1. Three-dimensional model of pathway constructed of clear polytetrafluoroethylene tubing simulating the intracranial carotid circulation.

through a tortuous pathway constructed of Teflon tubing shaped to simulate the intracranial arterial circulation.

Methods

State-of-the-art microcatheters were provided by four manufacturers for evaluation in this study. Catheters tested include the FasTracker MX 18 (Target Therapeutics, Fremont, CA), the Jetstream 18 (Medtronic/Microinterventional Systems, Sunnyvale, CA), the Rapid Transit (Cordis Endovascular Systems, Miami, FL), the TurboTracker 18 (Target Therapeutics, Fremont, CA), and the Venture 2 (Meditech/Boston Scientific, Natick, MA). All test catheters were obtained from commercially available stock and, when possible, catheters of multiple lots were tested.

A three-dimensional pathway simulating the intracranial carotid circulation was constructed of clear polytetrafluoroethylene tubing (Zeus, Orangeburg, SC) with an internal diameter of 0.065 in. (Fig 1). A total of four turns (two with a radius of 0.5 in. and two with a radius of 0.25 in.) were used to simulate the internal carotid artery circulation. The entire pathway, mounted on a plexiglass board, was immersed in an 8 × 14 × 28-in. water bath maintained at 37°C. Continuous circulation within the bath was maintained with the use of a Brinkman water pump (Brinkman Instruments, Westbury, NY). Water within the tubing was refreshed between each catheter pass by manual injection of water from the bath by using a hand-held syringe.

All load testing was performed using an Instron tabletop load frame (Model No. 4465) fitted with a 2-lb load cell. This device is designed to measure load forces as the catheter and guidewire combination is advanced at a constant, predetermined rate, selected to simulated rates of catheter advancement that would be reasonable in clinical practice.

A single 0.014-in. stainless steel noncoated guidewire was used for all testing. Preliminary testing of the guidewire consisted of 50 passes through a 22-cm segment of the pathway at a rate of 8 in. (203 mm) per minute. This same wire was then inserted into a microcatheter with the wire protruding 1 cm from the catheter tip. This microcatheter and guidewire system was advanced 50 times through the pathway at a rate of 8 in. (203 mm) per minute. The wire alone was next advanced through the pathway an additional 50 times under the same parameters. These preliminary tests were performed to determine whether a single guidewire could be used for the entire study or whether degradation and shaping of the wire would occur. Additional wire tests, consisting of multiple passes of the guidewire only, were performed after testing of each manufacturer's catheters. Because no changes in the characteristics of the guidewire were detected, a single 0.014-in. wire was used throughout the study. Integrity of the guidewire was confirmed with multiple passes of the guidewire alone, performed after completion of all catheter testing.

Fig 2. Proximal buckling of the FasTracker MX catheter because of excessive load forces.

At least four sample microcatheters from each manufacturer were tested. The guidewire tip was extended ½-in. beyond the microcatheter for all testing. All catheters except for the Rapid Transit were obtained from at least two different lots. The first of each manufacturer's catheters was passed through the 22-cm tortuous pathway 50 times at a speed of 2 in. (50.8 mm) per minute. Load forces were sampled at a rate of four points per second. At least three additional catheters from each manufacturer were passed through the pathway, three times each at a rate of 8 in. (203 mm) per minute. Load forces for these three sample catheters were recorded, statistically analyzed for variation between samples, averaged, and graphically displayed.

Because of excessive buckling of the proximal catheter shaft (Fig 2), fewer runs were performed with the FasTracker MX, and several of these runs were aborted early. At the manufacturer's recommendation, multiple passes of the FasTracker MX catheters were attempted using a Mach-16 guidewire (Target Therapeutics) at displacement speeds of 2 and 8 in. per minute. Once again, buckling of the system prevented completion of the full testing protocol. Testing of a fifth microcatheter, the TurboTracker 18, was performed at a later date at the manufacturer's request. This reinforced catheter was not commercially available at the time of our original testing. The TurboTracker was subjected to the identical conditions as the other four manufacturers' catheters. Testing was performed using the original 0.014-in. stainless steel guidewire.

Differences between brands of catheters were analyzed using a one-way analysis of variance at specific displacement

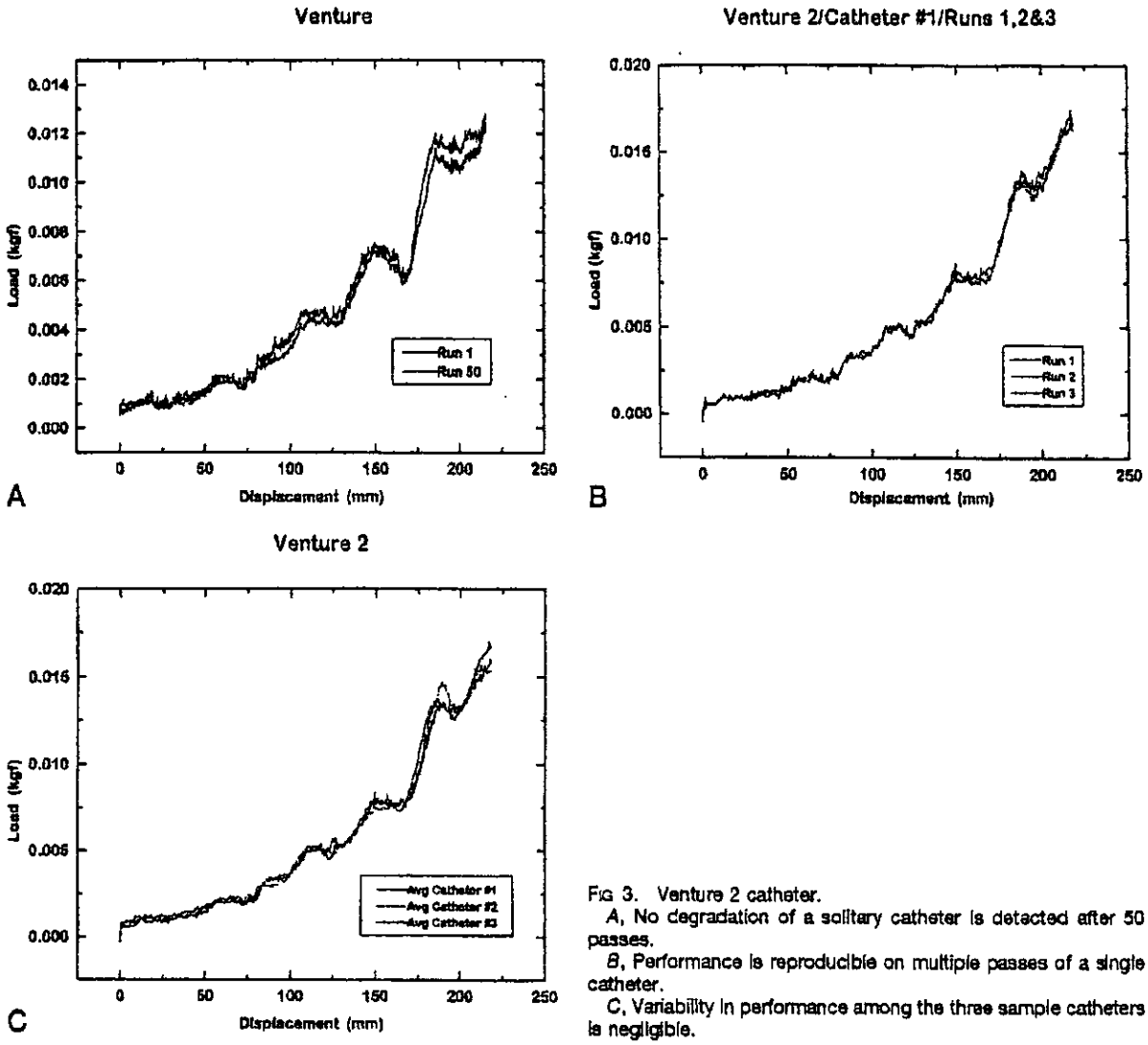


FIG 3. Venture 2 catheter.
A, No degradation of a solitary catheter is detected after 50 passes.
B, Performance is reproducible on multiple passes of a single catheter.
C, Variability in performance among the three sample catheters is negligible.

points. *P* values for multiple comparisons tests were adjusted using the Bonferroni correction. Displacements of 60, 90, 117, 150, and 190 mm were chosen for the analysis, since these displacement points seem to correspond to load peaks related to curves in the tortuous path.

Results

Extensive testing of the guidewire established reproducible performance throughout the pathway, with maximum load forces of approximately 8 g. The load profile and maximum load forces were not significantly changed, even at the termination of the experiment. No evidence of permanent deformity or shaping was noted regarding the solitary guidewire used throughout the entire experiment.

Testing of the Venture 2 microcatheter established a profile that paralleled that of the guidewire alone, but with slightly higher load forces. The average maximum load force for the three sample catheters measured at 190 mm of displacement was 13.8 g. No degradation in catheter performance was noted after 50 passes of the first sample (Fig 3A). There was no discernible variation between several runs of the same catheter (3B), nor was there any perceptible variation in the performance of three additional Venture 2 sample catheters (3C).

Testing of the Rapid Transit and Jetstream 18 microcatheters produced similar performances to the Venture 2, but with even lower average maximum gram forces for the three sample catheters at 190 mm displacement, measuring 9.7 and 9.3 g, respectively. Once again, no degradation of either brand microcatheter was noted after 50 passes, nor was there any significant variability between individual catheters from the same manufacturer.

Testing of the FasTracker MX was complicated by excessive catheter buckling, which was overcome early in the pathway in a staccato, stepwise fashion (Fig 4). After reaching a critical frictional force, however, the catheter and guidewire buckled irrecoverably, necessitating the termination of the test. This characteristic was observed with each of five FasTracker microcatheters at rates of both 2 and 8 in. per minute. The maximum load at the termination of these runs was measured as high as 69.9 g. Excessive buckling was again encountered, even when the study

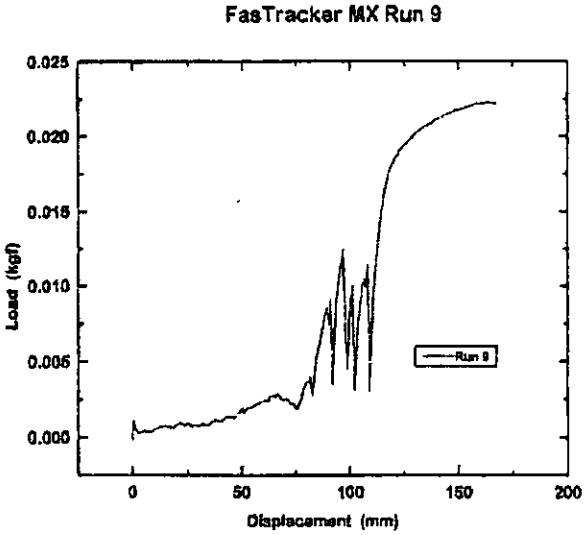


Fig 4. FasTracker MX catheter. Multiple load peaks corresponding to multiple successive episodes of buckling and paroxysmal advancement of the catheter are observed between 75 and 110 mm of displacement. Above 110 mm of displacement, the catheter buckled in an irrecoverable manner, with an excessive increase of load forces to over 20 g.

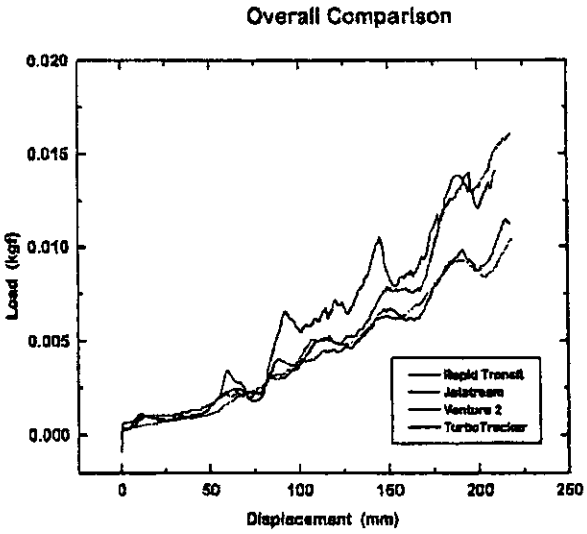


Fig 5. Overall comparison of the four reinforced catheters. Average load forces required by three catheters (three passes of each) are plotted against displacement. Lower maximum load forces are required by the Jetstream and Rapid Transit catheters but may not be clinically significant.

was repeated using a Mach-16 guidewire at the manufacturer's suggestion.

No degradation in performance was noted in the TurboTracker after 50 passes. The average load force for the three samples of this microcatheter at 190 mm of displacement was 13.1 g, approximating the performance of the Venture 2.

At 60 mm of displacement into the pathway, statistically significant differences in load force ($P < .05$) were found between the Rapid Transit and the Jetstream, between the TurboTracker and the Jetstream, between the TurboTracker and the Rapid Transit, and between the TurboTracker and the Venture 2. At a displacement of 90 cm, significant differences in load force were found between the TurboTracker and all other catheters. At 117 mm of displacement, significant differences in load force were found between the TurboTracker and the Jetstream, and between the TurboTracker and the Rapid Transit. At very distal displacements of 150 and 190 mm, no significant difference between catheters could be statistically determined (Fig 5; see Table).

Average load forces (g) for three samples of each brand of reinforced catheter at selected displacement values

	Displacement, mm				
	60	90	117	150	190
Jetstream	1.7	3.0	5.0	6.3	9.3
Rapid Transit	2.3	3.9	4.5	6.7	9.7
TurboTracker	3.4	6.0	6.3	8.5	13.1
Venture 2	2.1	3.2	5.3	7.7	13.8

Discussion

Factors that impact in vivo microcatheter performance include lubricity, stiffness, and durability. Different manufacturers use various catheter materials, hydrophilic coatings, and mechanical designs to optimize the safety and trackability of their catheter systems. Designing an in vitro model that does not fatigue or change with use, but that simulates the intracranial carotid circulation, is a difficult task. The shape of our model was designed to provide a reasonable degree of frictional resistance against catheter advancement and to roughly simulate the curvature of the intracranial carotid circulation. Polytetrafluoroethylene tubing was chosen as a moderately rigid, nonfatiguing material. Although a similar model might have been constructed from cadaveric human or animal arterial specimens, such a model would be difficult to standardize throughout a lengthy and repetitive testing protocol and might have introduced errors into our experiment. Although it lacks some of the distensibility of an in vitro arterial segment, we thought that polytetrafluoroethylene tubing was a reasonable material from which to construct a pathway that would not confound our measurements of catheter performance. Potential transfer of hydrophilic coating from the multiple microcatheters to the Teflon could occur; however, the tubing was manually flushed after passage of each catheter. Furthermore, the lowest average gram forces were recorded with passage of the Jetstream microcatheter. This catheter was passed through the system 50 times in the preliminary phase of guidewire testing and again as the third of five manufacturers' catheters being tested. No appreciable difference in performance of this brand of microcatheter was detected at these various times in the study, suggesting that our results are in fact due to intrinsic properties of the catheters rather than to any change in the tortuous pathway.

The Jetstream 18, Rapid Transit, TurboTracker,

and Venture 2 microcatheters are all supported by an integral braid or coil. Performance between and within the sample groups of the Jetstream, Rapid Transit, and Venture 2 was good and reproducible, paralleling performance of the guidewire alone. Performance of the TurboTracker established more run-to-run variability for each catheter, as well as variability in performance between different sample catheters of the same brand.

Diminished load forces were actually required by the Jetstream and Rapid Transit catheters after the first pass of each sample (Fig 6). This phenomenon may be the result of the softening of the catheter in the water bath, the softening of the hydrophilic coating with hydration, or the microfracture of the hydrophilic coating with the first pass. This first-pass effect was not noted with the TurboTracker or Venture 2 catheters.

Performance of the FasTracker MX, the only nonbraided catheter we tested, was markedly inferior in this model. We believe that the lack of integral reinforcement leads to buckling of the microcatheter when the tip encounters the points of greatest resistance within the tortuous pathway (ie, the curves). This effect is transmitted in a retrograde fashion along the microcatheter, resulting in severe buckling of even the stiffer proximal portion of the shaft. Early in the pathway, the still relatively low frictional forces are overcome by the catheter in a staccato fashion, resulting in small forward jumps of the distal tip. This performance characteristic may have implications for intracranial catheterization, in which unexpected forward advancement of the microcatheter may result in perforation of small vessels or a cerebral aneurysm. Although differences in hydrophilic coatings could be implicated to account for the performance difference between the reinforced catheters and the FasTracker, we think that the basic differences in catheter shaft construction are far more important. Further testing is planned to compare the lubricity of these different catheters and hydrophilic coatings and the forces required to overcome static friction.

Various techniques are used in clinical practice to facilitate the advancement of the microcatheter/guidewire combination. One of the most commonly used techniques has been to take advantage of the catheter slack that accumulates in tortuous vascularity by withdrawing the guidewire a significant distance into the catheter and then advancing it again in a smooth fashion. This often propels the catheter tip forward as the guidewire is being advanced. Various catheters may respond differently to this maneuver. This type of complex manipulation could not be reliably simulated by the load frame device and was not assessed in our model. Such maneuvers may significantly contribute to the clinical performance of certain types of microcatheters and may account for the clinical acceptance of nonreinforced microcatheters, such as the FasTracker.

Statistical analysis among brands of catheters disclosed significant differences between the TurboTracker and the other catheters at displacement values of 60, 90, and 117 mm. Nevertheless, no statistical model can accurately predict the clinical performance of a particular brand of catheter. Load forces were relatively small for all reinforced catheters, and the actual clinical performance of all catheters tested is acceptable to various groups of skilled interventionists.

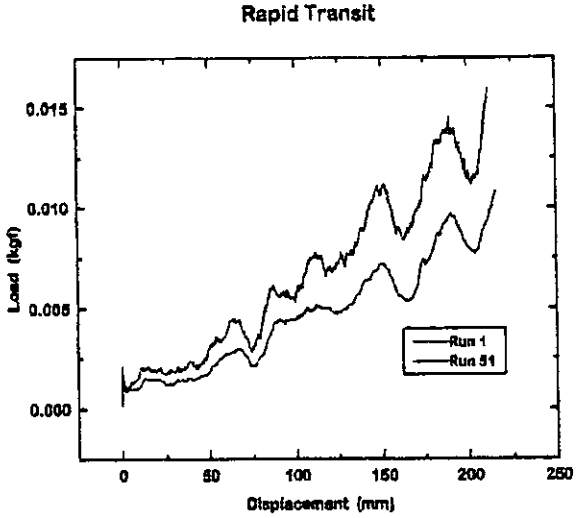


FIG 6. Load forces required by the Rapid Transit catheter actually diminish with multiple passes. This effect, which can be observed after only one or two passes, also occurred with the Jetstream catheter. Improvement may be the result of the softening of either the catheter or the hydrophilic coating.

Lower load forces may cause less vascular trauma during intracranial catheterization. Rupture of a cerebral aneurysm proximal to the tip of a microcatheter has been attributed to stretching and displacement of the proximal vasculature during attempted embolization of an arteriovenous malformation (AVM) (8). Unexpected, rapid advancement of the microcatheter tip during intraaneurysmal catheterization for diagnostic evaluation or coil embolization may result in perforation of the dome. Smooth and predictable advancement of the microcatheter tip is necessary to avoid this complication. The potential for perforation of an arterial feeder to an AVM during superselective catheterization has been acknowledged by some authors (9). Subarachnoid hemorrhage resulting from catheter perforation of a feeding artery during AVM embolization has also been documented by several investigators (10–12).

Conclusion

Testing of five state-of-the-art hydrophilically coated microcatheters was performed in a standardized tortuous pathway designed to simulate the intracranial carotid circulation. All reinforced microcatheters tested established good and reproducible performance in our model, requiring relatively small load forces to achieve smooth and predictable advancement. Thorough testing of a single brand of nonreinforced microcatheter could not be accomplished because of excessive buckling. The use of a catheter system with optimal trackability may en-

hance the safety of superselective intracranial catheterization.

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Harry J. Cloft, MD, PhD
Talisa A. Altes, MD
William F. Marx, MD
Robert J. Raible, MD
Sarah B. Hudson, BS
Gregory A. Helm, MD, PhD
James W. Mandell, MD
Mary E. Jensen, MD
Jacques E. Dion, MD, FRCPC
David F. Kallmes, MD

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From the Departments of Radiology (H.J.C., T.A.A., W.F.M., R.J.R., M.E.J., J.E.D., D.F.K.), Neurosurgery (G.A.H., S.B.H.), and Pathology (J.W.M.), University of Virginia Health Sciences Center, Received April 13, 1998; revision requested July 1; final revision received December 16; accepted April 8, 1999. T.A.A. is supported by the RSNA Research and Education Foundation as a 1997 Research Resident. D.F.K. is supported by the RSNA Research and Education Foundation as a 1997 Bracco/RSNA Scholar. Address reprint requests to H.J.C., Department of Radiology, Emory University Hospital, 1364 Clifton Rd NE, Atlanta, GA 30322 (e-mail: *harry_cloft@emory.org*).

Author contributions:
Guarantor of integrity of entire study, H.J.C.; study concepts and design, H.J.C., T.A.A., D.F.K.; definition of intellectual content, H.J.C., T.A.A., D.F.K.; literature research, H.J.C., T.A.A., D.F.K.; experimental studies, H.J.C., T.A.A., W.F.M., R.J.R., G.A.H., M.E.J., J.E.D., D.F.K.; data acquisition, all authors; manuscript preparation, H.J.C.; manuscript editing, H.J.C., D.F.K.; manuscript review, T.A.A., W.F.M.

Endovascular Creation of an in Vivo Bifurcation Aneurysm Model in Rabbits[1]

PURPOSE: To develop a rabbit model of an intracranial bifurcation aneurysm to test new endovascular therapies.

MATERIALS AND METHODS: An experimental aneurysm model was created in rabbits by means of endovascular balloon occlusion of the left common carotid artery, which created an aneurysm at the bifurcation formed by the aortic arch and the brachiocephalic trunk. A total of 18 aneurysms were created. In eight rabbits, the aneurysms were incubated with intraluminal elastase to induce degeneration of the elastic laminae. The animals were followed up with angiography for as long as 3 months. The animals were sacrificed at various times, and histologic evaluation of the aneurysm was performed.

RESULTS: Ten aneurysms created without elastase infusion were all very small or completely closed at 1–3 months. Six aneurysms created with elastase infusion had long-term patency (two were patent at 1 month and four at 3 months). The elastase aneurysms had a mean width of 3 mm (range, 2–3.5 mm) and a mean length of 5 mm (range, 3–7 mm). Histologic evaluation revealed destruction of the normal elastin layers, which allowed the artery to become aneurysmal.

CONCLUSION: This aneurysm model re-created the hemodynamic forces and size of human cerebral bifurcation aneurysms and maintained the integrity of the endothelium. The creation of the aneurysms was rapid, reliable, and reproducible.

The Guglielmi detachable coil (Boston Scientific Target, Natick, Mass) recently approved by the U.S. Food and Drug Administration was first tested in vivo in a swine model of lateral aneurysms (1). However, this swine model and most existing animal models fail to reproduce the hemodynamic forces in human intracranial aneurysms, which typically are bifurcation aneurysms. The creation of a vascular surgical wound also alters the response of the animal to the coil, since the open wound and disrupted basement membrane allow fibroblasts and other cellular elements to migrate into the lumen. This type of cellular migration is not known to occur in human intracranial aneurysms. In addition, the construction of most of the animal models currently used require tedious, labor-intensive vascular surgery. The purpose of this study was to develop a rabbit model of an intracranial bifurcation aneurysm to test new endovascular therapies.

MATERIALS AND METHODS

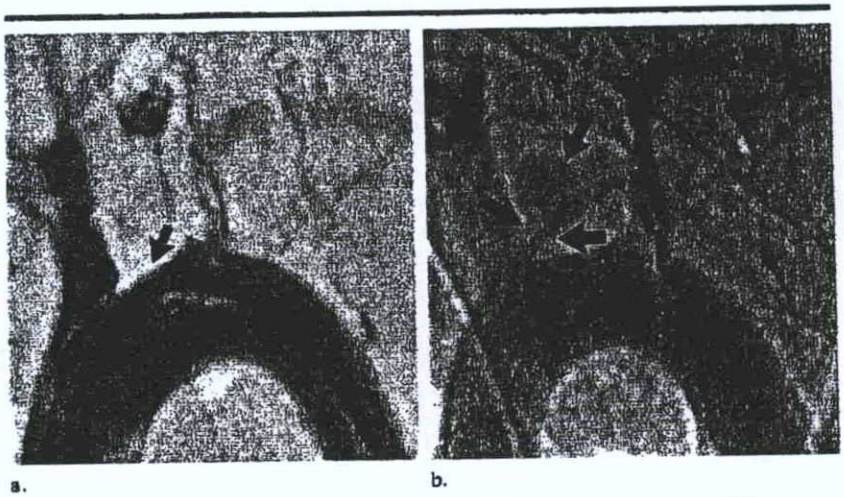
Eighteen New Zealand White rabbits (body weight, 3–4 kg) underwent a protocol approved by the animal research committee of our institution. Anesthesia was induced with an intramuscular injection of a mixture of ketamine hydrochloride (Ketaved; Vedco, St Joseph, Mo; 30 mg per kilogram of body weight) and xylazine hydrochloride (Tranquived; Vedco; 6 mg/kg). Maintenance anesthetic was administered via an ear vein with pentobarbital sodium (Nembutal; Abbott Laboratories, North Chicago, Ill; 1 mg/kg). In 10 animals, control models were created without the intraarterial infusion of elastase. In eight animals, aneurysm models were created with an elastase infusion, as described later.

Creation of Aneurysms without Elastase

The right inguinal region of each rabbit was shaved and prepared in a sterile manner. The right superficial femoral artery was exposed at surgery and was accessed with a 20-gauge Teflon sheath,

and an 0.018-inch–diameter guide wire was placed. Serial dilations were performed, and a 6-F sheath was placed.

A 6-F Envoy guiding catheter (Cordis Endovascular, Miami Lakes, Fla) was placed into the left common carotid artery. A hand-tied detachable latex balloon (no. 15 Debrun; Nycomed, Paris, France) was mounted on a microcatheter (Tracker-18; Boston Scientific Target). The balloon and microcatheter system was placed coaxially through the guiding catheter into the left common carotid artery. The balloon was inflated in a position approximately 2 cm distal to the origin of the vessel. The balloon was detached in the usual fashion. The guiding catheter and sheath were removed, and the right superficial femoral artery was ligated with 2.0 silk suture. The skin incision was closed with Polysorb 3-0 absorbable suture (Ethicon, Somerville, NJ).



a. b.

Figure 1. Left anterior oblique aortograms of the aortic arch demonstrate (a) a model aneurysm created without elastase infusion, which is completely thrombosed (arrow) after 1 month, and (b) a model aneurysm (arrows) created with elastase infusion, which is patent after 3 months and which has a size and bifurcation anatomy similar to that of human cerebral aneurysms.

Creation of Aneurysms with Elastase

Because the aneurysms created without elastase infusion did not remain patent, elastase infusion was added to the procedure to destroy the elastic laminae and thereby prevent the arterial contraction that occurred after balloon occlusion. In eight rabbits, the experimental aneurysms were incubated with intraluminal elastase to induce degeneration of the elastic lamina in the wall of the aneurysm.

The following additions were made to the procedure described previously. After balloon detachment, the guiding catheter was maintained in place at the origin of the left common carotid artery. A 6-F guiding catheter (Cordis Endovascular) approximated the size of the vessel and occluded the origin, so a closed system was achieved. A Tracker-18 catheter (Boston Scientific Target) was advanced through the guiding catheter into the arterial stump. Fifty units of bovine type I pancreatic elastase (Sigma Chemical, St Louis, Mo) was infused into the arterial stump and was left in place for 30 minutes. The microcatheter was then removed, and the guiding catheter was advanced into the ascending aorta. The microcatheter, guiding catheter, and sheath were removed, and the right superficial femoral artery was ligated with 2.0 silk suture. The skin incision was closed with Polysorb 3-0 absorbable suture (Ethicon).

Follow-up for the Aneurysms Created without Elastase

Angiography was performed immediately before sacrificing the animals. Anesthesia was induced with an intramuscular injection of a mixture of ketamine and xylazine. Maintenance anesthesia was achieved by means of an intravenous infusion of pentobarbital via the ear vein. The left femoral artery was exposed at surgery, and a 5-F catheter was placed in the ascending aorta. Nonionic contrast material (Omnipaque [Iohexol]; Nycomed Amersham, Princeton, NJ) was injected for cut-film angiography. The rabbits were sacrificed with a lethal dose of intravenous pentobarbital. Five rabbits were sacrificed at 1 month after the creation of the aneurysm, and five rabbits were sacrificed at 2–3 months.

Follow-up for the Aneurysms Created with Elastase

After we conducted the experiment with creating aneurysms without elastase as described previously, we learned that evaluation of the model aneurysms could be performed with intravenous digital subtraction angiography instead of invasive catheter angiography. Intravenous digital subtraction angiography was performed by injecting 10 mL of the nonionic contrast material into an ear vein during digital imaging while the animal was sedated with an intramuscular injection of ketamine and xylazine. Intravenous digital subtraction angiograms were obtained at 2 weeks and at 1 month after the procedure in all animals except the two that were sacrificed immediately after the aneurysm was created.

Rabbits were sacrificed with a lethal dose of intravenous pentobarbital at various intervals after occlusion of the left common carotid artery, as follows: immediately after occlusion ($n = 2$), at 1 month ($n = 2$), and at 3 months ($n = 3$). One rabbit was allowed to survive so we could continue to monitor the long-term patency of the aneurysm. Repeat intravenous digital subtraction angiography was performed immediately prior to sacrificing those animals that were sacrificed at 3 months to facilitate correlation of angiographic and histologic findings.

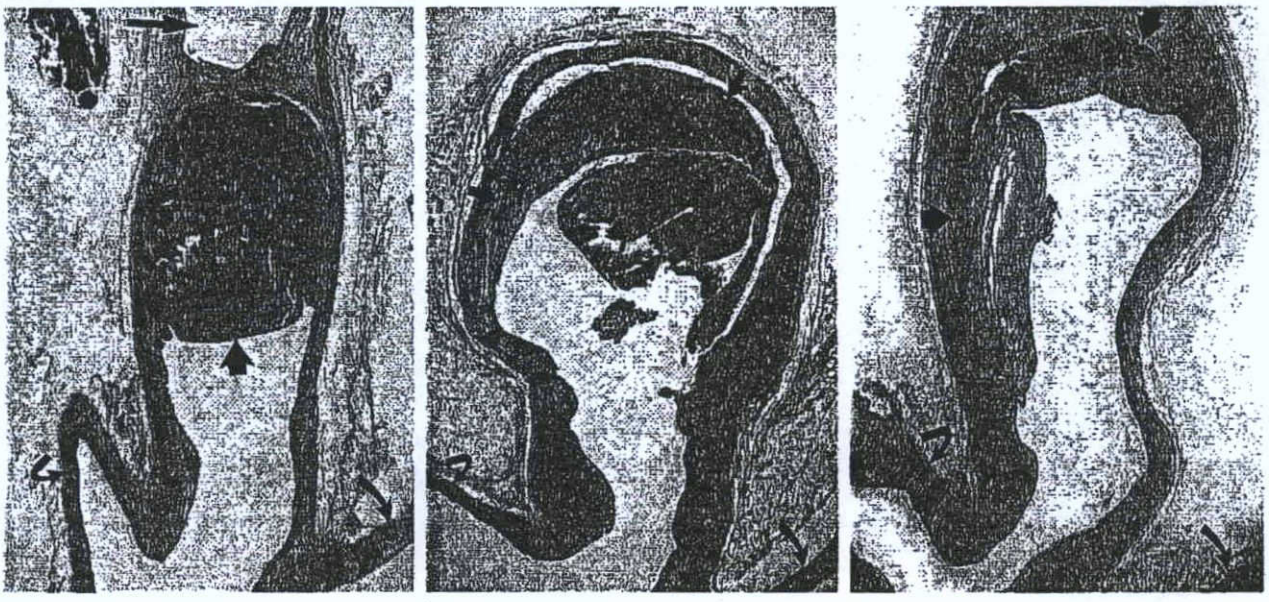
Histologic Evaluation

After the animals were sacrificed, the aortic arch and brachiocephalic vessels were excised and fixed with formalin. The specimens were embedded in paraffin and sectioned for histologic evaluation with hematoxylin-eosin and Verhoeff-van Giesen staining. The samples were evaluated by a pathologist (J.W.M.) for evidence of inflammation and thrombus formation and to determine the integrity of the elastic laminae.

RESULTS

Aneurysms Created without Elastase

All model aneurysms were patent immediately after creation. None of the aneurysms created without elastase infusion were more than minimally patent at angiography (Fig 1a) or at histologic evaluation (Fig 2a) performed at the time of sacrifice; the aneurysms measured only 1–2 mm in maximal dimension. The elastic laminae were intact (Fig 3a).



a. b. c.

Figure 2. Photomicrographs of model aneurysms oriented along the plane of the aortic arch depict histologic findings. (a) Without the elastase infusion, the model is mostly thrombosed (short straight arrow) and is without aneurysm dilatation after 1 month. The balloon occlusion site is seen above the thrombus (long straight arrow). (b) With the elastase infusion, the model has some chronic thrombus formation in the dome (straight arrows) and is aneurysmally dilated after 1 month. (c) After 3 months, the model remains patent and aneurysmal. Chronic clot (straight arrows) in the dome is again noted. In a–c, the curved arrow indicates the superior wall of the aorta, and the bent arrow indicates the brachiocephalic trunk. (Hematoxylin-eosin stain; original magnification, ×20.)

Aneurysms Created with Elastase

Two animals were sacrificed immediately after the creation of aneurysms with elastase infusion; therefore, they did not undergo follow-up angiography. The other six aneurysms created with elastase were imaged at digital subtraction angiography at 1 month and were shown to be patent. The sizes of the aneurysms are given in the Table. The experimental aneurysm, which consisted of the stump of the left common carotid artery, was located at the "bifurcation" of the brachiocephalic trunk and the aorta. The appearance of the four aneurysms that were imaged at digital subtraction angiography at 3 months (Fig 1b) was unchanged from the appearance at angiography performed at 1 month.

The models created with elastase infusion had chronic thrombus formation in the dome and were aneurysmally dilated after 1 month (Fig 2b). After 3 months, the models remained patent and aneurysmal, and chronic clot in the dome was again noted (Fig 2c). The vessel distal to the dome of the aneurysm was atrophic secondary to chronic occlusion. There was no inflammatory reaction in the walls of any of the model aneurysms. The elastic laminae persisted at the neck of the aneurysm but were destroyed at the distal portion (Fig 3b).

Clinical Sequelae

We noted no neurologic deficits secondary to the procedure in any of the rabbits. We also noted no systemic reaction to the elastase infusion.

DISCUSSION

We created a bifurcation aneurysm by occluding an artery at an arterial trifurcation with an endovascular technique. To maximize the size of, the hemodynamic forces within, and the flow into the aneurysm, we selected a trifurcation in the aortic arch. The left common carotid arterial stump was the aneurysm, with the brachiocephalic trunk and the aorta acting as the bifurcation branches. In New Zealand White rabbits, the left common carotid artery arose separately from the aortic arch in one-third of the cases and arose from the proximal brachiocephalic trunk in two-thirds of the cases (2). Both variations resulted in an aneurysm that arose essentially from a bifurcation.

Occlusion of the common carotid artery in rabbits could be performed without creating a neurologic insult because of the collateral blood flow to the brain via the circle of Willis. The jet of blood flow within the ascending aorta was directed at the orifice of the experimental aneurysm. This high-flow condition was expected to reduce thrombosis within the aneurysm and provide hemodynamic stresses similar to those in intracranial bifurcation aneurysms.

The aorta of the rabbit measured 4-5 mm, which was similar to the size of human carotid and basilar arteries. Therefore, it had a size that was appropriate for a parent vessel of an experimental aneurysm. The average size of the aneurysm created was 3 × 5 mm, which was well within the typical size range of human cerebral aneurysms and which was an appropriate size for endovascular therapy. On the angiograms obtained at 1 and 3 months, the size and shape of the aneurysms were unchanged.

Elastase was necessary to maintain the patency of the aneurysms. Without elastase, the occluded left common carotid artery contracted, which left no proximal stump to serve as an aneurysm model. Elastase administration presumably eliminated passive contraction of the artery after occlusion and thereby allowed it to dilate and form the aneurysm.

Other researchers have used the local application of elastase to induce or enlarge aneurysms. Anidjar et al (3) created fusiform aortic aneurysms in rats by using intraarterial incubation of porcine

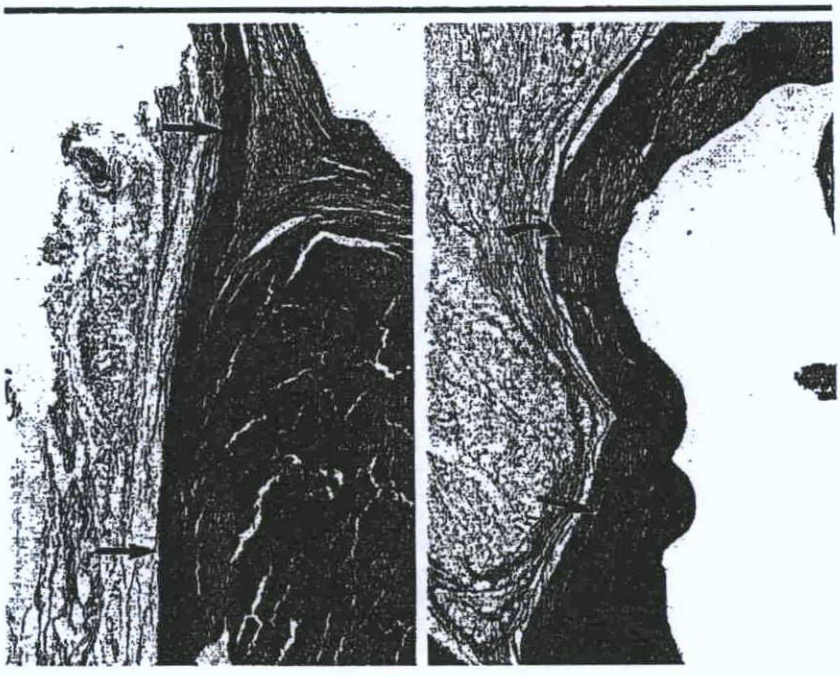
pancreatic elastase. Recently, this technique was extended to the creation of saccular aneurysms.

Cawley et al (4) created lateral aneurysms at surgery by ligating the external carotid artery near its origin and then by incubating the external carotid arterial stump with intraluminal porcine pancreatic elastase. The elastase disrupts the elastic lamina in the arterial wall. These aneurysms were followed for 2–12 weeks; 93% remained patent at angiography, and 40% were fully patent, without fibrin deposits or thrombus, at histologic evaluation. They speculated that the low patency rate was secondary to the low flow in the aneurysm. Their model has the advantages of a relatively simple surgical procedure, which is required for construction of the aneurysm, and an intact arterial wall. Recent data suggest that the morphology, cellular content, and appearance of the elastic lamina in these elastase-induced aneurysms are similar to those of human intracranial aneurysms (5).

Ideally, an experimental cerebral aneurysm should re-create the hemodynamic forces, physical dimensions, and radiographic appearance of human cerebral bifurcation aneurysms and should remain patent indefinitely, if untreated (6). In addition, the integrity of the endothelium should be maintained, and creation of the aneurysms should be rapid, reliable, and reproducible. The aneurysm model described in this report had all of these characteristics. This experimental bifurcation aneurysm was patent for at least 3 months after construction.

Although our technique was initially applied to the common carotid artery, it can be extended to other vascular trifurcations for the creation of bifurcation aneurysms with different sizes and flow characteristics. However, the size of the resultant aneurysm at other trifurcations in a rabbit would probably be small and would probably not be amenable to coil embolization. Trifurcations may exist in other animals, which would also allow formation of an aneurysm model amenable to coil embolization.

Surgical animal models of aneurysms have numerous shortcomings. Since bifurcation aneurysms are tedious to create at surgery (7), most surgical models rely on venous patch grafts that are sewn on straight segments. This procedure yields a lateral (or sidewall) aneurysm without the anatomic and hemodynamic characteristics typical of cerebral bifurcation aneurysms. Since the efficacy of an endovascular device such as the Guglielmi detachable coil is greatly influenced by hemodynamic forces at the aneurysm orifice (8), accurate modeling of hemodynamics is critical to creating a valid animal model.



a. b.

Figure 3. Photomicrographs of model aneurysms, obtained 1 month after creation of the aneurysms, are oriented along the plane of the aortic arch and depict histologic findings. (a) Without the elastase infusion, the elastic laminae (arrows) are intact. (b) With the elastase infusion, the elastic laminae persist (straight arrow) at the neck of the aneurysm but are destroyed (curved arrow) distally. (Verhoeff-van Giesen stain for elastin fibers; original magnification, ×40.)

Sizes of Mature Model Aneurysms Created with Elastase Infusion

Animal No.	Time to Final Angiogram (mo.)	Angiographic Size (width × length)
1	1	3.5 × 5.0 mm
2	1	2.5 × 4.0 mm
3	3	3.5 × 7.0 mm
4	3	2.0 × 3.0 mm
5	3	3.0 × 5.0 mm
6	3	3.5 × 5.5 mm

In addition to the disadvantage of requiring tedious vascular surgery, use of the surgical method creates aneurysms with suture lines that encircle the neck of the aneurysm and close the vein pouch. This disruption of the endothelium causes the release of platelet-derived growth factor, among other factors, that leads to scarring and obliteration of the cavity of the aneurysm. Fibrotic scarring of vein-patch aneurysms is a considerable problem. Also, most investigators rely on more expensive swine or canine models because of the difficulty of performing surgical procedures in smaller animals.

Other methods of creating bifurcation aneurysms have been reported. A method conceptually similar to ours is that described by Roach (9) and by Boyce and Roach (10), in which a bifurcation aneurysm is created at the trifurcation of the abdominal aorta in dogs by surgically tying the canine tail (sacral) artery. The surgical creation of such an aneurysm requires access to the retroperitoneum, which is accomplished with a relatively simple vascular procedure. A limitation is that only the depth of the aneurysm, not the width of the orifice, can be varied experimentally. An advantage is that the wall of the aneurysm is arterial.

Like Roach (9), Boyce and Roach (10), and Cawley et al (4), we elected to create an aneurysm by occluding an arterial branch near its origin. This created an aneurysm with an arterial rather than a venous wall to better simulate the morphologic and histologic attributes of human intracranial aneurysms (5). Unlike the experimental aneurysms previously described, our experimental aneurysm was constructed primarily with endovascular techniques.

The Guglielmi detachable coil recently approved by the U.S. Food and Drug Administration was initially tested and

validated in a swine lateral aneurysm model (1). This study did not include untreated control aneurysms, and subsequent experience has shown that a high frequency of spontaneous thrombosis in the pig model can lead to misinterpretation of the results (11). Subsequently, the Guglielmi detachable coil was tested in canine lateral aneurysms (12), in which it demonstrated fibrotic changes within the aneurysm. Although this canine study also lacked a control group, lateral wall aneurysms in dogs appear to remain patent reliably for at least 12 weeks, if left untreated (13).

Aneurysms created at surgery in the lateral wall of the carotid artery in monkeys were treated with a Guglielmi detachable coil and were found to contain organized media-like tissue at 3 months; but again, no long-term untreated controls were included (14). A recent study of the Guglielmi detachable coil in surgically created bifurcation aneurysms in rabbits showed similar fibrotic changes within the aneurysm lumen (15).

Little is known about the histologic response to the Guglielmi detachable coil in human aneurysms. To our knowledge, the only published long-term histologic data appear in an article by Molyneux et al (16), who reported findings from two patients who died of causes unrelated to their aneurysms at 2 and 6 months after therapy. In both of these cases, unlike the cases in which the fibrotic scar was found in the animal models described previously, there was unorganized thrombus in the aneurysms, and there was no evidence of endothelialization in the neck of the aneurysm (16).

Possible explanations for the discrepancy between the animal and human data include the following: (*a*) Humans have an unusual histologic response to the platinum coil compared with that of animals, or (*b*) the animal model is invalid. The animal model could be invalid if the surgical wound at the neck of the aneurysm leads to a fibrotic reaction to the coil in animals that does not occur in humans, who have no such wound at the neck of the aneurysm. The endovascular model described here would be more valid than existing models if it did not elicit the fibrotic reaction previously described.

A valid animal model that reproduces the human response to embolic materials in aneurysms is essential for the further improvement of the Guglielmi detachable coil and other materials. The formation of soft, unorganized clot rather than a fibrotic scar in human aneurysms that are treated with a Guglielmi detachable coil may be a major factor in coil compaction and regrowth of the aneurysm after embolization.

Attempts have been made to improve the treatment of aneurysms with and to modify the biologic response to the Guglielmi detachable coil with ion implantation (17), collagen filaments (13,18), and collagen coatings (19). Because these modifications were tested in animal models that did not simulate the biologic response to the conventional Guglielmi detachable coil in human aneurysms, the results of these experiments reveal little about how these modifications might affect therapy for human aneurysms.

Our model is not a perfect simulation of intracranial aneurysms in humans. The tunica media of the model aneurysm was intact, unlike that of cerebral aneurysms, and cells from the tunica media could affect the biologic response to embolic materials. In addition, the model aneurysm is not surrounded with cerebrospinal fluid within the subarachnoid space, but rather, it is surrounded with mediastinal tissues, which might affect the response to embolic materials in the lumen. However, the intact endothelium may function as a barrier between the lumen and the vessel wall and mediastinum, which prevents interference from cells and biologically active molecules that are not normally present in human cerebral aneurysms.

The model aneurysm had no arterial wall in its dome, but rather, it had only a blood clot. We did not consider such clot formation to be detrimental to our model, since many human aneurysms, especially those that have ruptured, have thrombus within them. Also, thrombus forms in surgical models of aneurysms (4,20). It is doubtful that the presence of clot was detrimental to the model, since the luminal surface of the model aneurysm that was in contact with embolic materials tested was similar, if not identical, to the luminal surface of cerebral aneurysms. This clot formed a barrier between the lumen and the balloon (or other embolic materials that could have been used, such as coils) and prevented interaction between the embolic material used to make the model aneurysm and the embolic material tested in the lumen of the aneurysm.

We report on an animal model of bifurcation aneurysms that accurately reproduced the hemodynamic forces and intact intima of human intracranial aneurysms and that was constructed with endovascular techniques. This model can facilitate the development and validation of new endovascular techniques for the treatment of human intracranial aneurysms. The long-term natural history of these model aneurysms beyond 3 months remains to be determined. It is doubtful that the aneurysms will rupture, since fusiform carotid aneurysms created with elastase perfusion in rabbits did not rupture during a 3-month follow-up (21). The blood pressures in rabbits are typically 90–130 mm Hg systolic and 80–90 mm Hg diastolic (22), which are within the normotensive ranges for adult humans. Blood pressure is important because it could affect blood clotting, clot maturation, and coil compaction.

Practical application: We are currently treating experimental aneurysms, created with the technique described here, with the Guglielmi detachable coil to evaluate their response. These aneurysms will be followed for 6 months to assess evidence of coil compaction. At the end of the observational period, a histologic examination will be performed. Experiments can then be performed with a Guglielmi detachable coil that has been modified to alter the biologic response to the coil and to reduce the risk of recurrence of aneurysms in humans.

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