

16093397

510(k) Summary

DEC 17 2009

Trade Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

Generic Name: Guidewire

Classification: Class II, 21 CFR 807.1330

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California U.S.A.

Contact: Naomi Gong

Predicate Devices:

Number	Description	Clearance Date
K080863	Traxcess 0.014" Hydrophilic Guidewire	April 7, 2008
K080563	Runthrough NS Extension Wire	March 20, 2008

Device Description:

The Traxcess 14EX Guidewire consists of a 0.014" stainless steel shaft and a tapered nitinol tip contained within 0.012" platinum and stainless steel coils. The distal coil section contains a lubricious hydrophilic coating, and the proximal shaft section is coated with PTFE and silicone.

The Traxcess Docking Wire is an accessory used to extend the Traxcess guidewire. It consists of a stainless steel shaft with a nitinol pipe and is coated with PTFE and silicone.

Indication For Use:

The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Verification and Test Summary Table

Bench Testing	Result
Physical attributes	Pass
Distal tip tensile strength	Pass
Tip flexibility	Pass
Distal tip torque strength	Pass
Coating adherence	Pass
Torqueability	Pass
Attachment with docking wire	Pass
Docking wire tensile strength	Pass

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Traxcess 14EX Guidewire and Traxcess Docking Wire when compared with the predicate devices.

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 material and processes.

In summary, the Traxcess 14EX Guidewire and Traxcess Docking Wire 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
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Microvention Inc.
c/o Ms. Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

DEC 17 2009

Re: K093397
Trade Device Name: Traxcess 14EX Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: December 11, 2009
Received: December 14, 2009

Dear Ms. Gong:

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

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

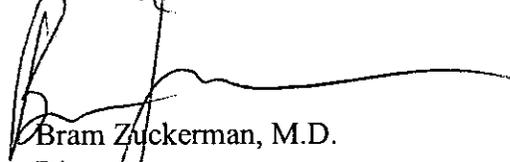
Page 2 - Ms. Naomi Gong

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

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

MicroVention, Inc.

Special 510(k), Traxcess EX

Indications for Use

510(k) Number (if known): K093397

Device Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

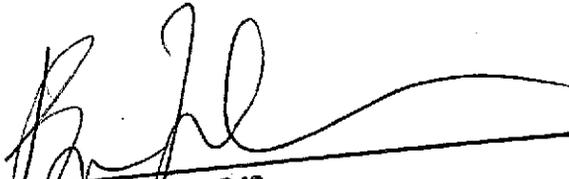
Indications For Use:

The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K09 3397



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Microvention Inc.
c/o Ms. Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

DEC 17 2009

Re: K093397
Trade Device Name: Traxcess 14EX Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: December 11, 2009
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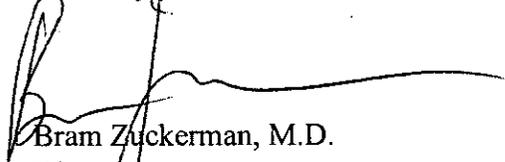
Page 2 - Ms. Naomi Gong

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

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MicroVention, Inc.

Special 510(k), Traxcess EX

Indications for Use

510(k) Number (if known): K093397

Device Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

Indications For Use:

The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

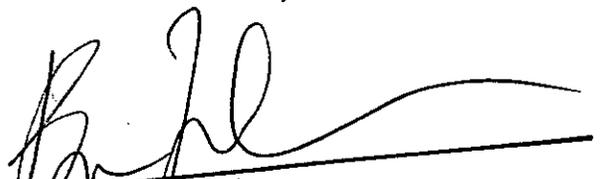
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093397



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

NOV 24 2009

Microvention Inc.
c/o Ms. Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K093397
Trade Name: Traxcess 14EX Guidewire
Dated: October 29, 2009
Received: October 30, 2009

Dear Ms. Gong:

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:

(b)(4)

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Page 2 – Ms. Naomi Gong

(b)(4)

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.

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Page 3 – Ms. Naomi Gong

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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>.

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

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

If you have any questions concerning the contents of the letter, please contact Nicole Ibrahim at Nicole.Ibrahim@fda.hhs.gov or (301) 796-5171. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address

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

Sincerely yours,



Kenneth Cavanaugh, PhD, Chief
Peripheral Vascular Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Page 4 – Ms. Naomi Gong

K093397

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DCD/PVDB	Ibrahim	11/24/09			
DCD/PVDB	Cavanagh	11/24/09			

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 02, 2009

MICROVENTION, INC.
 1311 VALENCIA AVE
 TUSTIN, CALIFORNIA 92780
 UNITED STATES
 ATTN: NAOMI GONG

510k Number: K093397

Received: 10/30/2009

Product: TRAXCESS 14EX GUIDEWIRE AND TR

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

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

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

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

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

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

Sincerely,

510(k) Staff

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1043397



U.S. Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

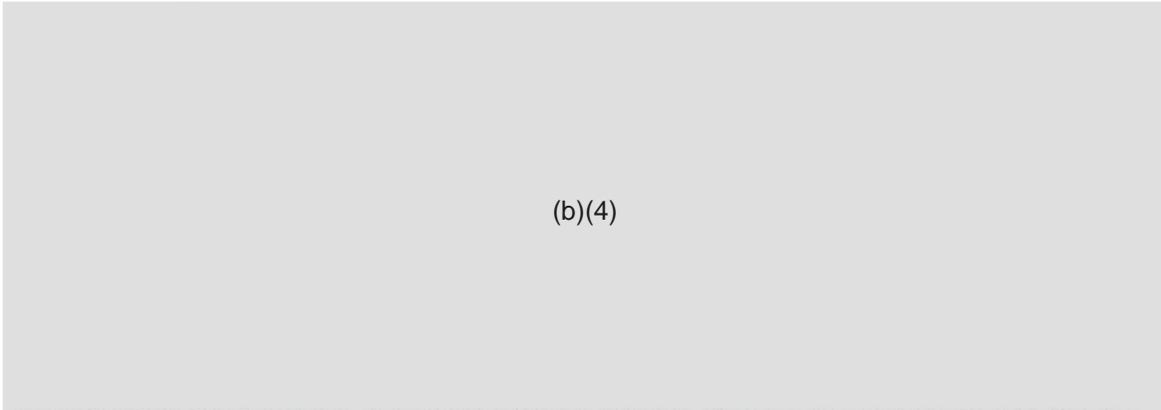
October 29, 2009

RE: **Special 510(k) Notification:** Traxcess 14EX Guidewire and Traxcess Docking Wire
Predicate device: Traxcess 0.014" Hydrophilic Guidewire (K080863)
Runthrough NS Extension Wire (K080563)
Classification: II
Regulation Number: 21 CFR 870.1330
Product Code: DQX
Classification Committee: Cardiovascular

Received
OCT 30 2009
FDA CDRH DMC

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. - Terumo hereby submits this Special Premarket Notification 510(k) for the Traxcess 14EX Guidewire and the Traxcess Docking Wire. MicroVention-Terumo is a wholly owned subsidiary of Terumo Medical Corporation (Elkton, MD).



(b)(4)

Included in this submission, is an electronic copy as per FDA's web instructions and it is an exact duplicate of the paper copy. The paper copy and electronic copy constitute the two copies required to be submitted for the 510(k) application. An additional original of this cover letter is provided for the electronic copy.

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.

K25



Thank you in advance for your consideration of our application. If there are any questions, please contact me at (714) 247-8055 or (949) 282-3742

A handwritten signature in black ink, appearing to read "Naomi Gong", written over a horizontal line.

Naomi Gong
Regulatory Affairs Project Manager
Tel: (714) 247-8055 or (949) 282-3742
eFax: (714) 247-8014
naomi.gong@microvention.com



U.S. Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 29, 2009

RE: **Special 510(k) Notification:** Traxcess 14EX Guidewire and Traxcess Docking Wire
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Thank you in advance for your consideration of our application. If there are any questions, please contact me at (714) 247-8055 or (949) 282-3742

Naomi Gong
Regulatory Affairs Project Manager
Tel: (714) 247-8055 or (949) 282-3742
eFax: (714) 247-8014
naomi.gong@microvention.com

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1. FDA Forms

1.1. Medical Device User Fee Cover Sheet

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MICRO VENTION INC 1311 Valencia Avenue Tustin CA 92780 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3774	2. CONTACT NAME Florin Truuvert 2.1 E-MAIL ADDRESS florin.truuvert@microvention.com 2.2 TELEPHONE NUMBER (include Area code) 949-680-5061 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 714-247-8014	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		15-Oct-2009

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

1.2. CDRH Submission Coversheet FDA 3514

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 10/29/2009	User Fee Payment ID Number MD6045744-956733	FDA Submission Document Number (if known)
----------------------------------	--	---

SECTION A TYPE OF SUBMISSION

<p>PMA</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p>PMA & HDE Supplement</p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	<p>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p>510(k)</p> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p>Meeting</p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (<i>specify</i>):
<p>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Other Submission</p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (<i>describe submission</i>):

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 MicroVention, Inc.	Establishment Registration Number (if known) 2032493		
Division Name (if applicable)	Phone Number (including area code) (714) 247-8055		
Street Address 1311 Valencia Avenue	FAX Number (including area code) (949) 247-8014		
City Tustin	State / Province CA	ZIP/Postal Code 92780	Country USA
Contact Name Naomi Gong			
Contact Title Regulatory Affairs Project Manager		Contact E-mail Address naomi.gong@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		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Additional models in the Traxcess Guidewire family					

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	DQX	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K080863	1	Traxcess 14 Guidewire	1	MicroVention, Inc. (Terumo) 1311 Valencia Avenue Tustin, CA 92780
2	K080563	2	Runthrough NS Extension Wire	2	Terumo Corporation 150 Maimaigi-cho Fujinomiya Shizuoka, Japan
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
Catheter guidewire

	Trade or Proprietary or Model Name for This Device		Model Number
1	Traxcess 14EX Guidewire	1	GW1420040X
2	Traxcess Docking Wire	2	GW14100EX
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

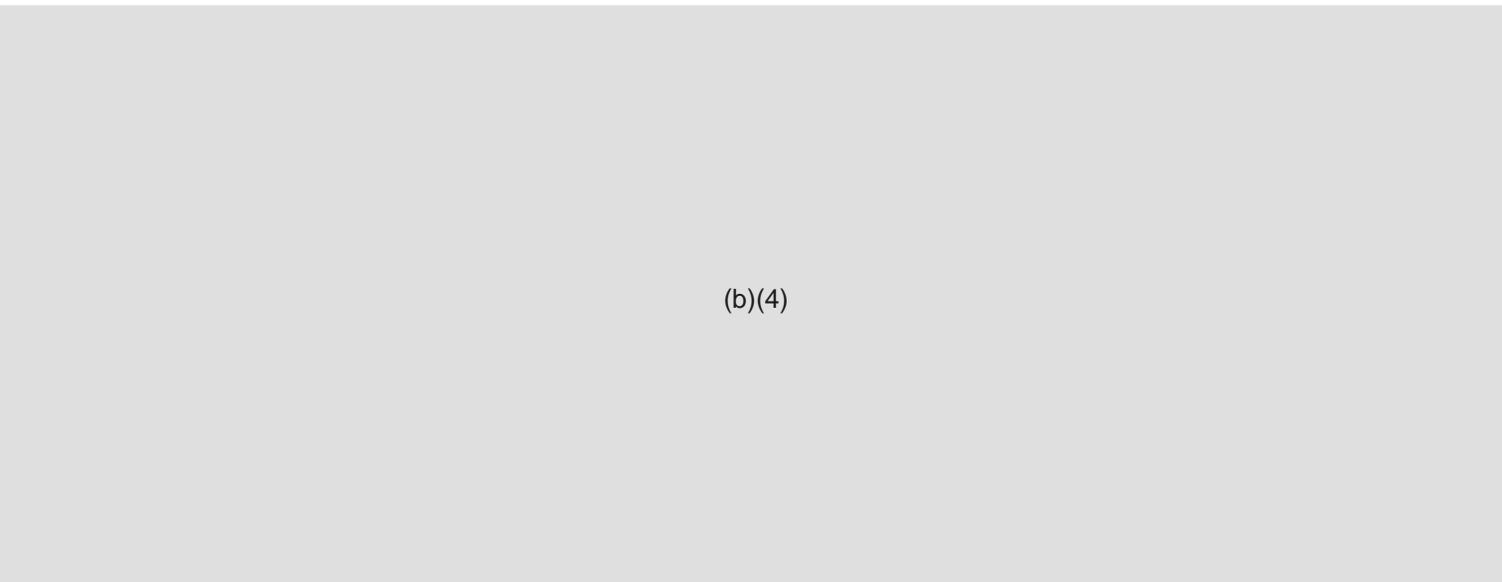
Data Included in Submission
 Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code DQX	C.F.R. Section (if applicable) 21 CFR 870.1330	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Cardiovascular Devices		

Indications (from labeling)
 The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device 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 <i>(if known)</i>	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number 2032493	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name MicroVention, Inc. (Terumo)		Establishment Registration Number 2032493	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> (714) 247-8055	
Street Address 1311 Valencia Avenue		FAX Number <i>(including area code)</i> (714) 247-8014	
City Tustin	State / Province CA	ZIP/Postal Code 92780	Country USA
Contact Name Naomi Gong	Contact Title Regulatory Affairs Project Manager	Contact E-mail Address naomi.gong@microvention.com	



(b)(4)

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> ()	
Street Address		FAX Number <i>(including area code)</i> ()	
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					
2					
3					
4					
5					
6					
7					

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

1.3. Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Project Manager 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)

Naomi Gong _____
(Typed Name)

(Date)

1.4. 510(k) Summary

510(k) Summary

Trade Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

Generic Name: Guidewire

Classification: Class II, 21 CFR 807.1330

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California U.S.A.

Contact: Naomi Gong

Predicate Devices:

Number	Description	Clearance Date
K080863	Traxcess 0.014" Hydrophilic Guidewire	April 7, 2008
K080563	Runthrough NS Extension Wire	March 20, 2008

Device Description:

The Traxcess 14EX Guidewire consists of a 0.014" stainless steel shaft and a tapered nitinol tip contained within 0.012" platinum and stainless steel coils. The distal coil section contains a lubricious hydrophilic coating, and the proximal shaft section is coated with PTFE and silicone.

The Traxcess Docking Wire is an accessory used to extend the Traxcess guidewire. It consists of a stainless steel shaft with a nitinol pipe and is coated with PTFE and silicone.

Indication For Use:

The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Verification and Test Summary Table

Bench Testing	Result
Physical attributes	Pass
Distal tip tensile strength	Pass
Tip flexibility	Pass
Distal tip torque strength	Pass
Coating adherence	Pass
Torqueability	Pass
Attachment with docking wire	Pass
Docking wire tensile strength	Pass

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Traxcess 14EX Guidewire and Traxcess Docking Wire when compared with the predicate devices.

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 material and processes.

In summary, the Traxcess 14EX Guidewire and Traxcess Docking Wire described in this submission is, in our opinion, substantially equivalent to the predicate device.

1.5. Indication for Use

MicroVention, Inc.

Special 510(k), Traxcess EX

Indications for Use

510(k) Number (if known): _____

Device Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

Indications For Use:

The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

MicroVention, Inc.

Special 510(k), Traxcess EX

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

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER <input type="text" value="Naomi Gong"/>	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="text" value="October 29, 2009"/>
3. ADDRESS (Number, Street, State, and Zip Code) <input type="text" value="MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780"/>	4. TELEPHONE AND FAX NUMBER (Include Area Code) (T) <input type="text" value="+1 (714) 247-8005"/> (F) <input type="text" value="+1 (714) 247-8014"/>

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)

<input type="text" value="Traxcess 14EX Guidewire (Model # GW1420040X)"/>	<input type="text"/>
<input type="text" value="Traxcess Docking Wire (Model # GW14100EX)"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

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)

<input type="text"/>					
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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)

Confidential

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 Naomi Gong Regulatory Affairs Project Manager
13. ADDRESS (Number, Street, State, and Zip Code) (of person identified in #11 & 12) 1311 Valencia Avenue Tustin, CA 92780	14. TELEPHONE AND FAX NUMBER (Include Area Code) (T) +1 (714) 247-8055 (F) +1 (714) 247-8014

15. DATE OF CERTIFICATION October 29, 2009

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
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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.

MicroVention, Inc.

Special 510(k), Traxcess EX

1.7. Form FDA 3654

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 TITLE¹

AAMI/ANSI/ISO 10993-1

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-98

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Draft Guidance on 510(k) submission for short and long-term Intravascular Catheter (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 and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>◊ 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.</p>		
Paperwork Reduction Act Statement		
<p>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:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>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.</i></p>		

1.8. Declaration of Conformity

Declaration of Conformity With Design Controls

Traxcess 14EX Guidewire and Traxcess Docking Wire

Verification Activities:

To the best of my knowledge, the verification activities required by the risk analysis, for the above referenced device were performed by the designated individual(s) in accordance with the MicroVention Quality Assurance Procedure Design and Development Process requirements, and the results demonstrated that the predetermined acceptance criteria were met.



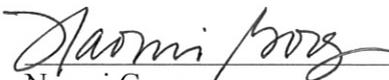
Shawn O'Leary
Director of Research and Development
MicroVention, Inc

10/29/2009
Date

=====

Manufacturing Facility:

The manufacturing facility, MicroVention Inc., is in conformance with the design control requirements as specified in 21 CFR 820.30, and the records are available for review.

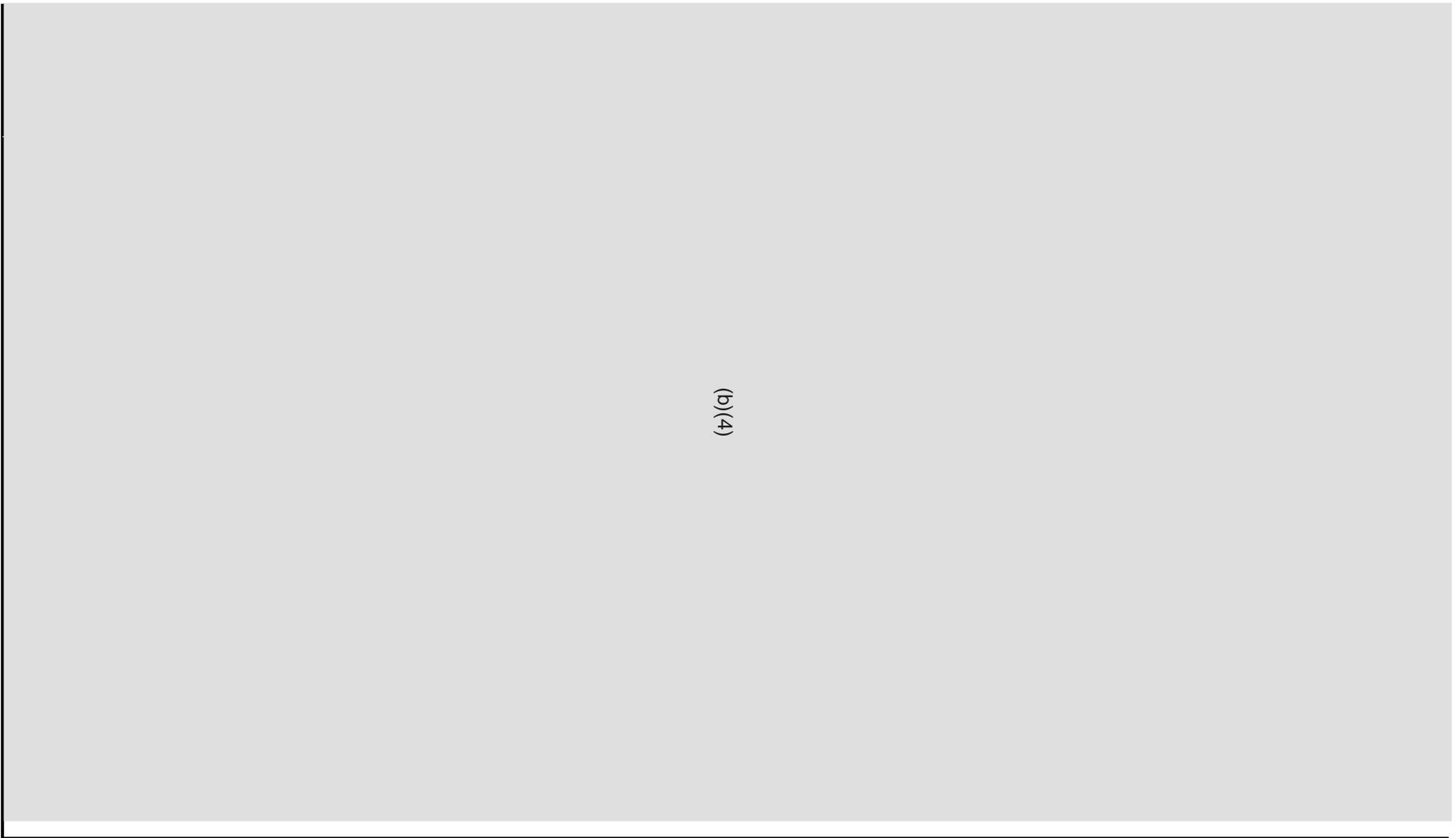


Naomi Gong
Regulatory Affairs Project Manager

10/29/2009
Date

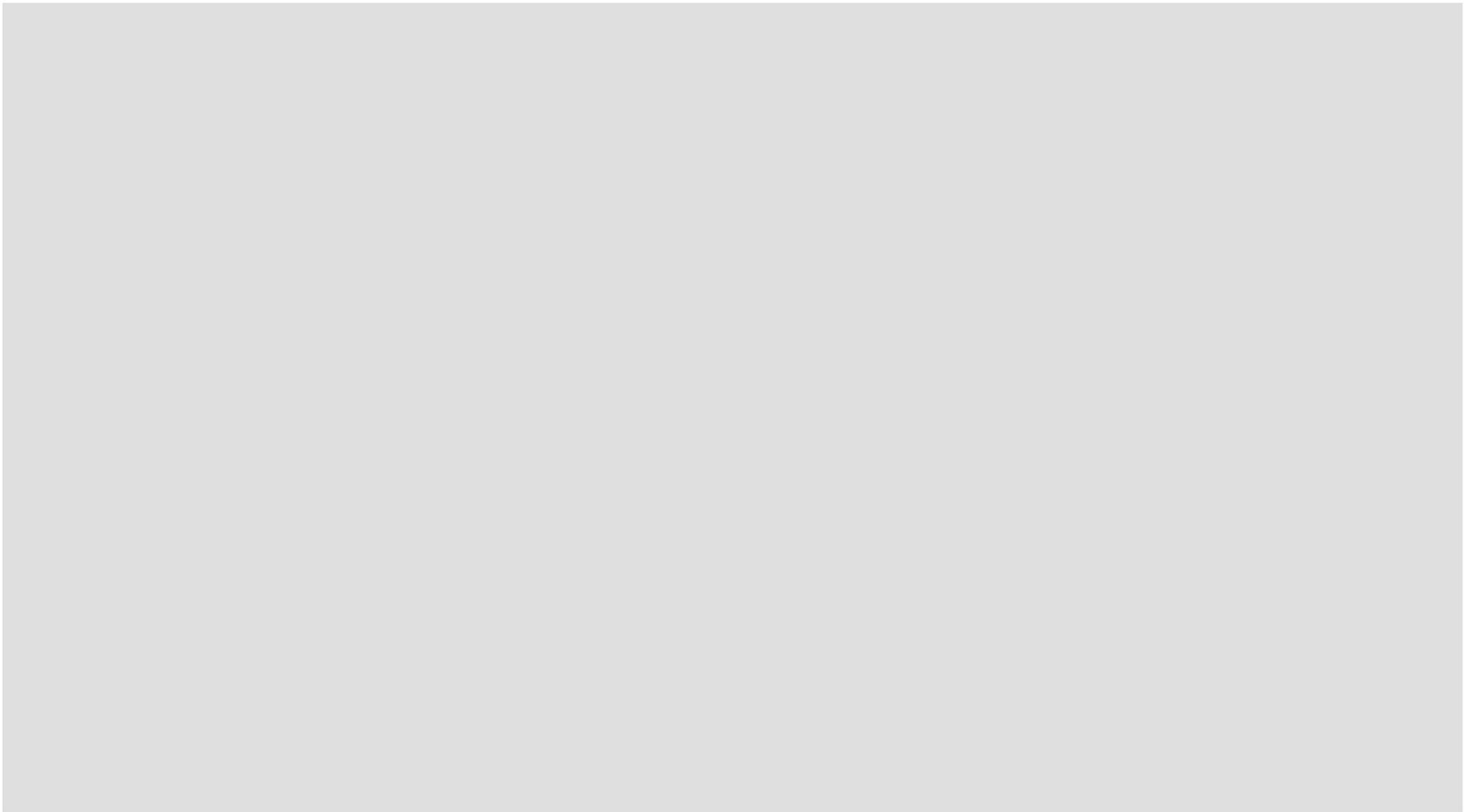
1.9. Design Control Activities Summary

Traxcess14EX Guidewire - Design Control Activities Summary



(b)(4)

Traxcess Docking wire - Design Control Activities Summary



2. Executive Summary

The MicroVention-Terumo Traxcess 14EX Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

The Traxcess 14EX consists of a proximal 0.014" diameter stainless steel shaft and a distal tapered nitinol wire contained within 0.012" diameter platinum and stainless steel coils. The distal coil surface is coated with a lubricious hydrophilic coating and the proximal shaft section is coated with PTFE/silicone. The proximal end is tapered in order to connect to the Traxcess Docking Wire. The distal 14 mm of the guidewire is shapeable by the physician. A shaping mandrel, inserter, and torque device are included with the device.

- The Traxcess 14EX Guidewire is substantially equivalent to the predicate, Traxcess 14 Guidewire [aka Traxcess 0.014' Hydrophilic Guidewire] (K0800863) in terms of design, construction of materials, and function. They are both made of the same materials and coated with the same hydrophilic and PTFE/silicone coatings.

The Traxcess Docking Wire is an accessory used to extend the overall length of the Traxcess guidewire for facilitating catheter replacement. To extend the guidewire length, the proximal end of the Traxcess guidewire is connected to the Traxcess Docking Wire. The Traxcess Docking Wire is removed when it is not needed. The Traxcess Docking Wire consists of a proximal stainless steel shaft and nitinol pipe (tube) attached at the distal end (diameter of 0.014"). The proximal shaft is coated with PTFE and silicone for lubricity. The Traxcess Docking Wire is provided sterile and sold separately.

- The Traxcess Docking Wire is substantially equivalent to the predicate, Terumo Runthrough NS Extension Wire (K080563). The Traxcess Docking Wire is identical to the Terumo Runthrough NS Extension Wire except that it is shorter in length. MicroVention-Terumo is a wholly owned subsidiary of Terumo Medical Corporation (Elkton, MD).

The *in vitro* testing covered the physical, mechanical, and functional performance of the Traxcess 14 EX guidewire using the FDA Special Controls Draft Guidance Document: Coronary and Cerebrovascular Guidewire Guidance, January 1995, and applicable sections of ISO 11070 international standard for Sterile, Single-Use Intravascular Catheter Introducers. These tests validated the performance characterization of the Traxcess 14EX compared to the predicate device, Traxcess 14. In addition, an acute animal study was conducted to further verify the performance of the Traxcess 14EX. The combined conclusion from these tests demonstrates that the *in vitro* behavior of Traxcess 14 is well characterized within design specifications. The Traxcess Docking Wire was also tested and the results demonstrated it met design specifications.

The Traxcess 14EX Guidewire and Traxcess Docking Wire are comprised of the same materials that are used in the existing Traxcess 14 (K080863). Biocompatibility

is based on the existing Traxcess 14 in which biocompatibility was established in accordance with ISO 10993-1 and provides assurance that the Traxcess 14EX, including the Traxcess Docking Wire, have a safe biocompatibility profile for use as a circulating blood device.

There is no change to the packaging and sterilization method. The Traxcess 14EX is packaged in the same packaging configuration as the existing Traxcess 14. The Traxcess Docking Wire is packaged in the same packaging configuration as the existing Runthrough NS Extension Wire. Both are sterilized using the same ethylene oxide (EO) gas sterilization method.

Lastly, there is no change to the intended use or Instructions for Use for the Traxcess 14 EX from the predicate Traxcess 14 (K080863). The Traxcess Docking Wire has the same intended use as the Traxcess 14. The Traxcess 14EX is to be sold sterile, for single use only, as well as the Traxcess Docking Wire.

It is on this basis that it can be concluded the safety profile of Traxcess 14EX and Traxcess Docking Wire is well within acceptable safety limits to be used for general intravascular use, including the neuro and peripheral vasculature.

MicroVention, Inc.**Special 510(k), Traxcess EX****3. Device Name**

The device trade names and common/classification names are:

Device Trade Name	Traxcess 14EX Guidewire Traxcess Docking Wire
Device Generic Name	Catheter guidewire
Classification Name	Catheter guidewire
CFR Classification	21 CFR 870.1330
Device Class	Class II
Classification Committee	Cardiovascular
Product Code	DQX

4. Address and Registration Number

The address and registration number of the manufacturer and sterilization sites for the device are:

Manufacturer	MicroVention, Inc. 1311 Valencia Avenue Tustin, California U.S.A
Establishment Registration No.	2032493
Contact	Naomi Gong Regulatory Affairs Project Manager 1311 Valencia Avenue Tustin, California U.S.A. Phone: (714) 247-8055 Fax: (714) 247-8014
Manufacturing and Sterilization Site	(b)(4)

5. Device Class

The Traxcess 14EX Guidewire and the Traxcess Docking Wire is a catheter guidewire and is classified as Class II, DQX.

6. Predicate Device Information

K080863, MicroVention-Terumo, Traxcess 0.014" Hydrophilic Guidewire
K080563, Terumo Runthrough NS Extension Wire.

7. Labeling and Intended Use

Draft labels and Instructions For Use are provided in [Attachment 1](#).

Intended Use

The intended use is the same as the predicate device and is stated in the product labeling as follows:

The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

8. Device Description

The MicroVention-Terumo Traxcess 14EX Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

The Traxcess 14EX consists of a proximal 0.014" diameter stainless steel shaft and a distal tapered nitinol wire contained within a 0.012" platinum and stainless steel coils. The distal coil surface is coated with a lubricious hydrophilic coating and the proximal shaft section is coated with PTFE/silicone. The distal 14 mm of the guidewire is shapeable by the physician. The proximal end is tapered in order to connect to the Traxcess Docking Wire. The distal 14 mm of the guidewire is shapeable by the physician. A shaping mandrel and torque device are included with the device.

The Traxcess Docking Wire is an accessory used to extend the overall length of the Traxcess guidewire for facilitating catheter replacement. To extend the guidewire length, the proximal end of the Traxcess guidewire is connected to the Traxcess Docking Wire. The Traxcess Docking Wire is removed when it is not needed. The Traxcess Docking Wire consists of a proximal stainless steel shaft and nitinol pipe (tube) attached at the distal end. The proximal shaft is coated PTFE and silicone for lubricity. Its overall diameter is 0.014".externally with PTFE for lubricity. The Traxcess Docking Wire is provided sterile and sold separately.

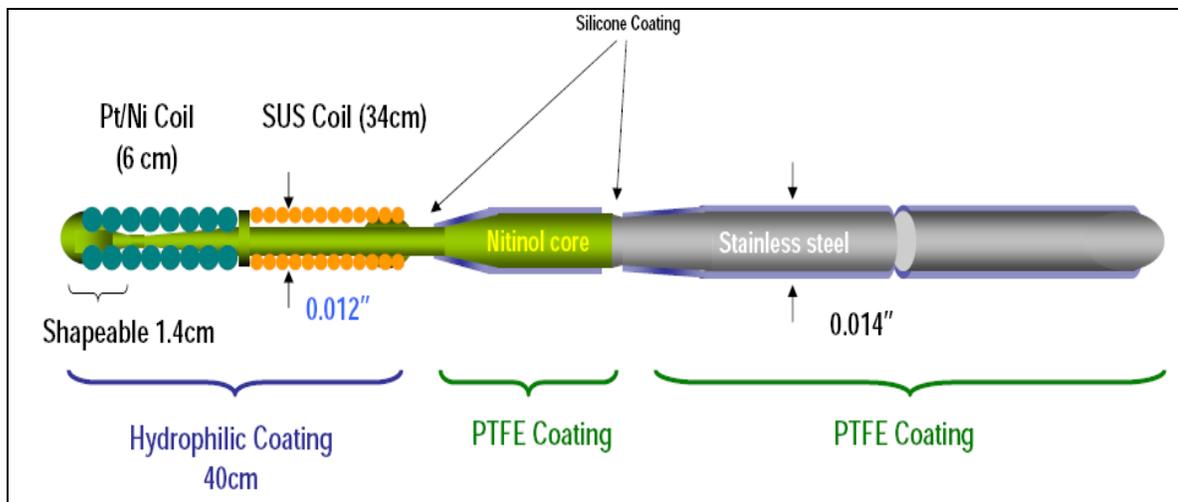
9. Device Configurations and Dimensions

The Traxcess 14EX Guidewire and Traxcess Docking Wire will be available under the following model numbers. The Traxcess Docking Wire is sold separately.

Device	Catalogue Number	Length	Distal Length (Shapeable)	Size (prox/distal)
Traxcess 14EX	GW1420040X	200 cm	14 mm	0.014"/0.012"
Traxcess Docking Wire	GW14100EX	115 cm	N/A	0.014"

10. Design Description

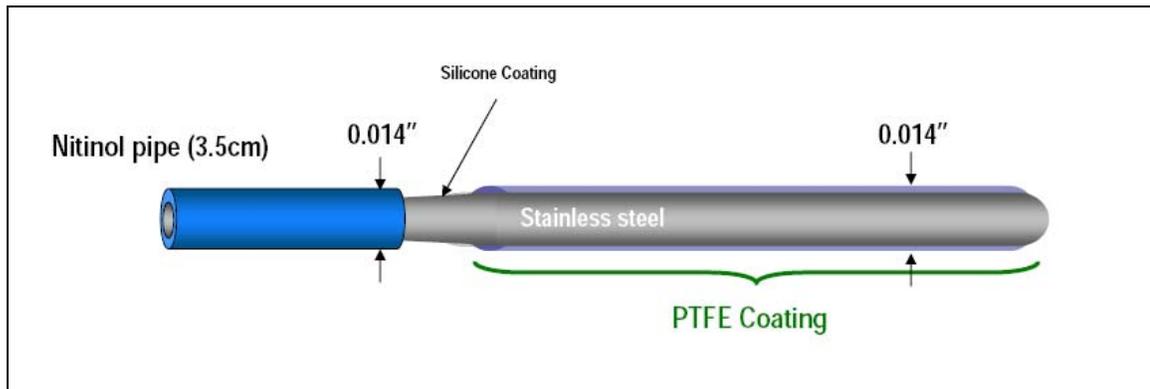
Similar to the Traxcess 14 guidewire, the Traxcess 14EX is a coil-type guidewire. It has a stainless steel shaft (proximal) of 0.014" diameter with a distal tapered nitinol wire contained within platinum and stainless steel coils (0.012" dia). The distal coil surface is coated with a lubricious hydrophilic coating and the proximal shaft section is coated with PTFE and silicone. The distal 14 mm is shapeable by the physician. The proximal end of the guidewire has been configured to be connected compatible with the Traxcess Docking Wire. Similar to the predicate device, a shaping mandrel, inserter, and torque device are also included.



Traxcess 14EX Guidewire

The Traxcess Docking Wire is an accessory used to extend the overall length of the Traxcess guidewire for facilitating catheter replacement. To extend the guidewire length, the proximal end of the Traxcess guidewire is connected to the Traxcess Docking Wire. The Traxcess Docking Wire is removed when it is not needed. Similar to the Terumo Runthrough NS Extension Wire, the Traxcess Docking Wire consists of a proximal stainless steel shaft and nitinol pipe (tube) attached at the distal

end. The proximal shaft is coated PTFE and silicone for lubricity. Its overall diameter is 0.014".externally with PTFE for lubricity. The Traxcess Docking Wire is provided sterile and sold separately. The only difference between the Traxcess Docking Wire and the Runthrough NS Extension wire is the length – the Traxcess Docking Wire is shorter in length.



Traxcess Docking Wire

Similar to the existing Traxcess 14 guidewire, there is no change to the intended use. There is no change to the basic design, materials, and construction of the device. Additionally, there is no change in the packaging and sterilization methods.

The Traxcess 14EX has maintained the same fundamental technological design as the predicate Traxcess 14. The differences between the two devices involve only the distal tip segment of the guidewire and are summarized below:

- Distal tip thickness of the core wire has been increased from 0.037 mm to 0.058 mm.
- Radiopaque (Pt/Ni) segment has been lengthened to 6 cm from 3 cm.
- Proximal end has been configured to be compatible with the Traxcess Docking Wire.
- Addition of the Traxcess Docking Wire as an accessory to the device.

The sample product drawings for the Traxcess 14EX and Traxcess Docking Wire are provided in the [Attachment 2](#).

11. Technological Characteristics Comparison

The following table compares the technological characteristics of the Traxcess 14EX to the predicate device, Traxcess 14.

	Existing Traxcess 14 (K080863)	Traxcess 14EX
Guidewire Attributes		
Intended Use	The Traxcess 14 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.	Same
Diameter	Proximal = 0.014" Distal = 0.012"	Same
Overall Length	200 cm	Same
Distal Shaft Length (Shapeable Length)	1.4 cm	Same
Material	Core wire (proximal): Stainless steel Core wire (distal): Nickel titanium alloy Coil: Stainless steel and Platinum nickel alloy Other: (b)(4)	Same
Coating	Shaft: PTFE/silicone Coil: Hydrophilic Coating (dimethylacramide-glycidyl methacrylate copolymer)	Same
Coil Length	40 cm	Same
Radiopaque Length	3 cm	6 cm
Distal tip thickness (core wire)	0.037 mm	0.058 mm
Proximal end configuration	Straight	Tapered to be compatible with Traxcess docking wire
Other attributes		
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Accessories	Shaping mandrel, torque device, and Inserter	Same
Package configuration	Placed into a dispenser hoop, tyvek pouch, and box carton.	Same

The following table compares the technological characteristics of the Traxcess Docking Wire to the predicate device, Runthrough NS Extension Wire.

	Existing Runthrough NS Extension Wire (K080563)	Traxcess Docking Wire
Guidewire Attributes		
Outer Diameter (OD)	0.014"	Same
Overall Length	120-165 cm	115 cm
Pipe Length	2-7 cm	3.5 cm
Material	Shaft: Stainless steel Pipe: Nickel titanium alloy Other (b)(4)	Same
Coating	PTFE Silicone	Same
Other attributes		
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Package configuration	Placed into a dispenser hoop, tyvek pouch, and box carton.	Same

12. Design Control and Risk Management Processes

The Traxcess 14 EX Guidewire and Traxcess Docking Wire are designed, developed and tested in accordance with the MicroVention Design and Development procedure in which the impact of modifications on device safety and performance is assessed in accordance with the ISO 14971-1 (Medical Device Risk Management) – Part 1, and with the MicroVention internal quality system procedure for risk management. Possible hazards and associated risk related to the device modification and clinical usage of the device were identified, examined and found to be acceptable after the implementation of the countermeasures such as physician training program, labeling warnings, specify possible mitigation.

Copies of the Design and Development and Risk Management Procedures, and the Headway 21 Risk Management document are included.

(b)(4)

13. List of Voluntary Standards

The Traxcess 14EX Guidewire and Traxcess Docking Wire was designed, developed, and tested using the applicable requirements of the following standards:

Standard No.	Standard Name	Edition
FDA Guidance	Coronary and Cerebrovascular Guidewire Guidance	1995
ISO 11070	Sterile, single use Intravascular Catheter Introducers	1998
Medical Device Directive	Council Directive 93/42/EEC	2003/2007
ISO/EN 14971	Medical Device – Application of Risk Management to medical devices	2007
ANSI/AAMI/ISO11135	Medical Devices- Validation and routine control of ethylene oxide sterilization, overkill method	2007
EN 556-1	Sterilization of medical devices, Requirements for medical devices designated “STERILE”	2001
ISO 13485	Particular requirement for application of ISO 9001	2003
ISO 10993-1	Biological evaluation of medical devices	2003
EN DIN 980	Graphical Symbol used in Labeling of Medical Devices	2003
ISTA 3A	ISTA (International Safe Transit Association) Procedure 3A- Performance Tests for Packaged Products for Parcel Delivery System 150 lbs (70 kg) or Less	2006
ISO 11607 -1, -2	Packaging for Terminally Sterilized Medical Devices	2006
EN 1041	“Terminology, Symbols and Information Supplied with Devices.”	1998

14. In-Vitro/Bench Verification

The Traxcess 14EX and Traxcess Docking Wire were tested and verified in the laboratory setting for required performance attributes.

All test samples met the established design specification criteria for parametric attributes as well as the determined confidence/reliability level for variable data.

Test Sample Configuration

Product	No. of Samples	Model
Traxcess 14EX	(b)(4)	GW1420040X
Traxcess Docking Wire		GW14100EX

14.1. Traxcess 14EX Guidewire

The Traxcess 14EX was tested and verified according to written protocol TP09-098, Traxcess 14EX Guidewire Design Verification. As presented in the test results

(b)(4)

14.1.1. Physical Attributes

Dimensional and physical attributes of the test samples were inspected and results met acceptance criteria.

14.1.2. Distal Tip Tensile Strength

The tensile strength of the distal tip of the guidewire was measured and the results of the tests met acceptance criteria.

(b)(4)	Distal Tip Tensile Strength
Mean	(b)(4)
Std dev.	
Maximum	
Minimum	
Specification	
Pass/Fail	

14.1.3. Tip Flexibility

With different tip spans (lengths), with a displacement of 2mm (flexing), the force was measured and compared to the predicate device. All test results met acceptance criteria at (b)(4) tip spans.

Tip Flexibility ((b)(4)

(b)(4)	
N	(b)(4)
Mean	
Std dev	
Maximum	
Minimum	
Specification	
Pass/Fail	

Tip Flexibility (b)(4)

N	(b)(4)
Mean	
Std dev	
Maximum	
Minimum	
Specification	
Pass/Fail	

Tip Flexibility (b)(4)

N	(b)(4)
Mean	
Std dev	
Maximum	
Minimum	
Specification	
Pass/Fail	

14.1.4. Distal Tip Torque Strength

The number of turns to guidewire failure were measured and compared to the predicate device. All results met acceptance criteria.

	Traxcess 14EX	Traxcess 14 (predicate)
N	(b)(4)	
Mean		
Std dev		
Maximum		
Minimum		
Specification		
Pass/Fail		

14.1.5. Coating Adherence

(b)(4)

N	(b)(4)
Mean	
Std dev	
Maximum	
Minimum	
Specification	
Pass/Fail	

Note: (b)(4)

14.1.6. Torqueability

(b)(4)

Difference between input and output angle

	Traxcess 14EX	Traxcess 14 (predicate)
N	(b)(4)	
Mean		
Std dev		
Maximum		
Minimum		
Specification		
Pass/Fail		

14.1.7. Particulate Testing per USP

(b)(4)

(b)(4)

Particulate Analysis

	(b)(4)
Sample 1	
Sample 2	
Specification	
Pass/Fail	(b)(4)

14.2. Traxcess Docking Wire

(b)(4)

14.2.1. Physical attributes

Dimensional and physical attributes of the test samples were inspected and results met acceptance criteria.

14.2.2. Attachment strength

The amount of force to separate the connection of the Traxcess Docking Wire from the guidewire was measured and results met acceptance criteria.

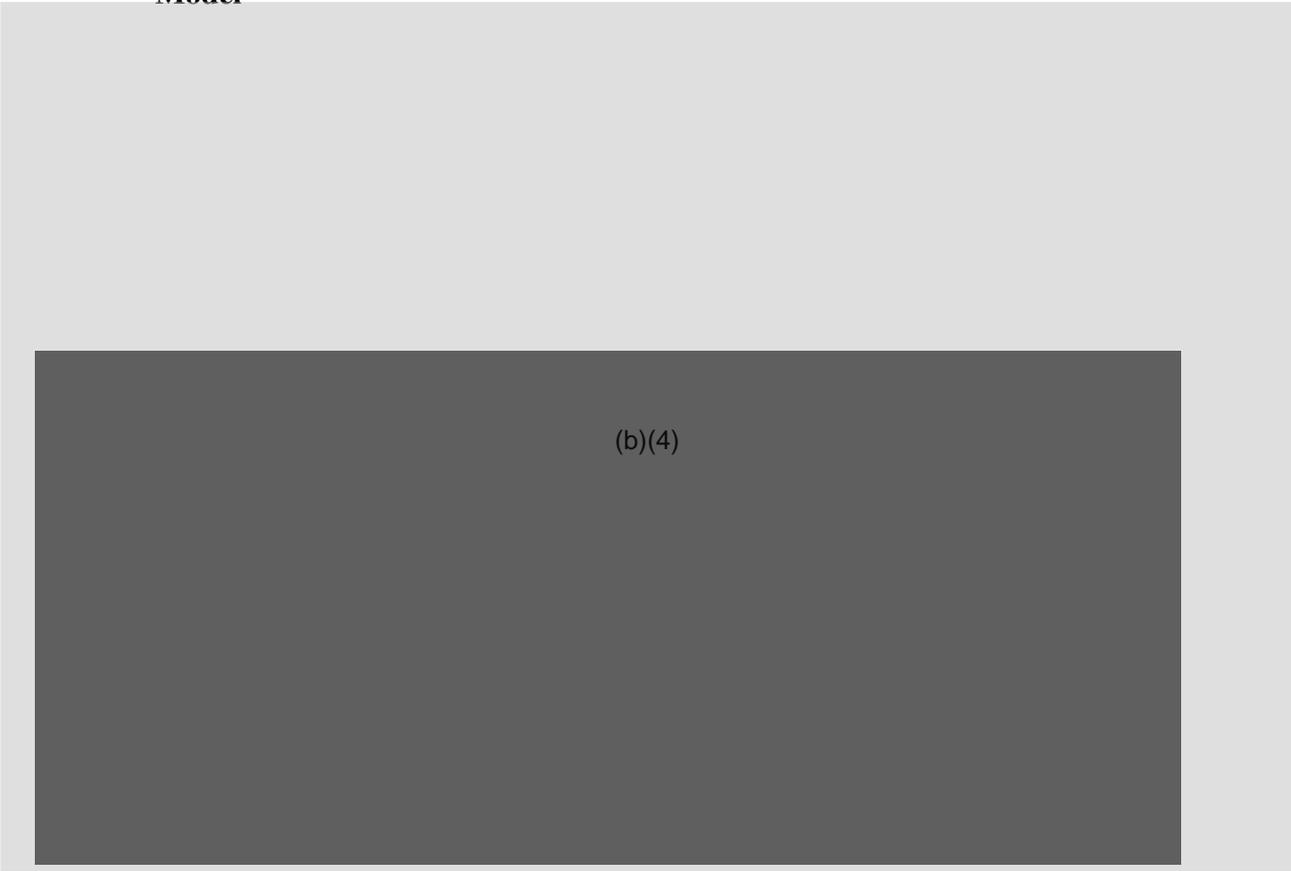
	Attachment Strength
Mean	(b)(4)
Std Dev	
Maximum	
Minimum	
N	
Specification	
Pass/Fail	

14.2.3. Tensile strength

The tensile strength of the Traxcess Docking Wire was measured and results met acceptance criteria.

	Tensile Strength
Mean	(b)(4)
Std Dev	
Maximum	
Minimum	
N	
Specification	
Pass/Fail	

14.3. *In-Vitro* “Simulated Use” Test in Simulated Intra-Cranial Silicone Flow Model



(b)(4)

Simulated Use and Repositioning per TM 260

(b)(4)	Tracking	Supportability	Microcatheter compatibility/exchange	Fatigue/Fracture/Flexing
Average	(b)(4)			
Std Dev				
Maximum				
Minimum				
N				
Specification				
Pass/Fail				

15. Preclinical Animal Testing

(b)(4)

16. Packaging, Sterilization, and Shelf Life

(b)(4)

(b)(4)

Packaging Configuration

Packaging	Existing Traxcess 14	Traxcess 14EX and Traxcess Docking Wire
Material	(b)(4)	
Package Configuration		
Method of Supplying		
Method of Sterilization		

No material changes have been made from the Traxcess 14 to warrant repeating of shelf-life studies on the Traxcess 14EX. Similar to the Traxcess 14, the shelf life for the Traxcess 14EX will be labeled for 3 years. The shelf life of Traxcess Docking Wire remains unchanged from the Terumo Runthrough NS Extension Wire which is also 3 years.

17. Biocompatibility

Biocompatibility studies were not repeated as the Traxcess 14EX Guidewire and Traxcess Docking Wire are made of the same materials that are used in the fabrication of existing Traxcess 14. The biological safety of the Traxcess 14EX is based on the existing Traxcess 14 in which biocompatibility was established in accordance with the ISO10993-1, Biological Evaluation of Medical Devices.

(b)(4)

Biocompatibility Summary

(b)(4)

(b)(4)

18. Sterilization

Ethylene Oxide Sterilization Process

The Traxcess 14EX is to be sold sterile, for single use only. The device is sterilized using ethylene oxide (EO) gas in the same manner as the Traxcess 14. Sterilization is

(b)(4)

The validation and routine EO sterilization of the Traxcess 14EX was performed in accordance with the requirement of the ANSI/AAMI/ISO11135-1994, Medical Devices- Validation and routine control of ethylene oxide sterilization, overkill method.

Sterilization Summary	
<i>Sterility Validation Method</i>	(b)(4)
<i>Sterilization Method</i>	
<i>Sterility Assurance Level</i>	
<i>EO Residuals</i>	
<i>Pyrogen Tests</i>	
<i>Sterilization Site</i>	

19. Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Traxcess 14EX and Traxcess Docking Wire when compared with the predicate devices: Traxcess 14 (K080863) and Runthrough NS Extension Wire (K080563)

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 material and processes.

In summary, the Traxcess 14EX guidewire and Traxcess Docking Wire described in this submission is, in our opinion, substantially equivalent to the predicate devices.

20. ISO/EC Certification and Compliance

MicroVention develops and manufactures their products under its certified quality system (ISO13485:2003, CMDCAS). All MicroVention products are developed and tested based upon design control procedures that include risk analysis, *in vitro*, *in vivo* and clinical studies (as appropriate). The MicroVention facility is US FDA registered as well as licensed by the California State Department of Health.

(b)(4)

21. List of Attachments

- Attachment 1** Product Labels, Instructions For Use
- Attachment 2** Product Drawing
- Attachment 3** QP 4.1, Design and Development Quality Procedure
- Attachment 4** QP 4.8, Risk Management Quality Procedure
- Attachment 5** RA05004, Risk Management File, Headway Microcatheter
- Attachment 6** TP/TR 09-098, Traxcess 14EX Design Verification
TR 09-176, Traxcess Docking Wire Bench Test
TP/TR 09-0137, Simulated Use Testing
- Attachment 7**..... TP/TR 09-0151, Rabbit Animal Evaluation
- Attachment 8**..... MicroVention - Terumo ISO Certificates

Traxcess™ Guidewire Instructions for Use

DEVICE DESCRIPTION

Traxcess Guidewire is a 0.014" diameter steerable guidewire consisting of a 0.012" diameter distal coil constructed of radiopaque platinum and stainless steel. The coil section is coated with a hydrophilic material for lubricity. The distal 14 mm of the coil tip is shapeable. The distal core wire consists of nitinol, and the proximal section is stainless steel. The proximal shaft section is coated with polytetrafluoroethylene (PTFE).

CONTENTS

One Hydrophilic Guidewire with Torque Device, Insertion Tool, and Shaping Mandrel.

INDICATIONS FOR USE

Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

There are no known contraindications.

CAUTIONS

Rx-Only: Federal law (USA) 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 guidewire is provided sterile and non-pyrogenic unless the unit package is opened or damaged.

The guidewire 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 guidewire prior to use for any irregularities or damage and discard if noted.

The guidewire should be manipulated under fluoroscopic guidance. Do not advance or withdraw the guidewire when excessive resistance is met until the cause of resistance is determined. Observe the tip response when turning the guidewire and avoid turning in the same direction more than three times when the tip is stationary. Avoid kinking the tip of the guidewire, as damage to the guidewire might occur.

PRECAUTIONS

Verify guidewire 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.

The guidewire has a lubricious surface and distal platinum coil section should be hydrated prior to use.

Exercise care in handling the guidewire to reduce the chance of accidental damage. Do not expose the guidewire surface to organic solvents such as alcohol or medications, which might damage the guidewire coatings and/or cause the guidewire to lose lubricity.

Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the guidewire is compatible with the outer diameter of the guidewire prior to use.

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.

Avoid repeated bending at the same point in order to avoid damage or separation of the guidewire.

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

PREPARATION FOR USE

Before removing the guidewire, hydrate the hydrophilic segment by flushing heparinized saline through the dispenser tube using a syringe attached to the dispenser tube hub (see Figure 1).

To prevent damage to the guidewire, gently remove the wire clip that holds the wire in place in the protective race track. Gently remove the guidewire by pulling it from the dispenser tube. If resistance is met, repeat the flushing procedure until the guidewire can be easily removed from the dispenser tube. Inspect the guidewire thoroughly to insure it is not damaged.

If tip shaping is desired, gently bend the distal tip using fingers or by winding the tip round the shaping mandrel as shown (Figure 2) until the desired shape is achieved.

Figure 1

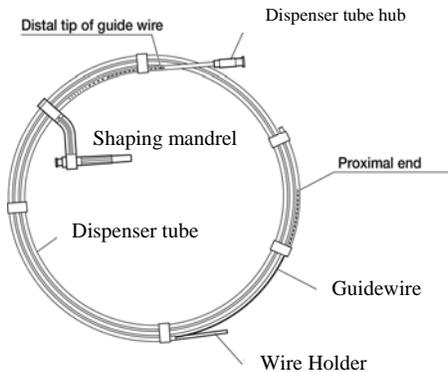
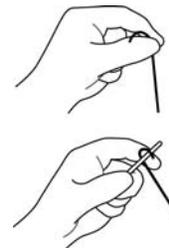


Figure 2



DIRECTIONS FOR USE

Prior to inserting the guidewire into the catheter, flush the catheter lumen with heparinized saline to prime the catheter and provide smooth movement of the guidewire within the catheter. A hemostatic Y-connector may be attached to catheter hub and used to facilitate the flushing process.

Carefully insert the distal section of the guidewire into the catheter and advance. A guidewire Insertion Tool may be used to facilitate insertion of the guidewire distal tip through a Y-adapter and into the catheter hub. Advance the Hydrophilic Guidewire until the distal tip is near the distal end of the catheter. Gently tighten the hemostatic Y-connector to maintain position.

Slip the torque device over the proximal end of the guidewire to the desired location. Secure the torque device in place by tightening the rotating knob. The torque device may be repositioned by loosening and retightening the rotating knob.

During navigation in the vasculature, loosen the hemostatic Y-connector, advance and rotate the guidewire by rotating the torque device in either direction to facilitate vessel selection. To aid in catheter navigation , gently rotate the guidewire as it is advanced.

Between uses, rinse the guidewire in a basin of heparinized saline and wipe it gently with sterile, wet gauze and place in a basin of heparinized saline or a flushed dispenser tube to keep the hydrophilic surface wet until use.

STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the guidewire 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 guidewire does not contain latex or PVC materials.

SYMBOLS

	Lot Number		Do Not Reuse
	Catalog Number		Use by Date
	Contents		Manufacturer
	Sterilized Using Ethylene Oxide		Authorized European Representative
	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.



Manufacturer:

MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780 USA
Tel: (714) 247-8000
www.microvention.com

Traxcess™ Docking Wire
Instructions for Use
For Use with the Traxcess™ Guidewire

For further instructions and information, refer to the Instructions for Use that accompanies the Traxcess Guidewire.

DEVICE DESCRIPTION

The Traxcess Docking Wire is a 0.014" diameter guidewire attachment consisting of stainless steel and nitinol. The shaft is coated with polytetrafluoroethylene (PTFE) for lubricity. The Traxcess Docking Wire is compatible with the Traxcess guidewire which has an extendable proximal end. The Traxcess Docking Wire is used to extend the guidewire for facilitating catheter replacement.

CONTENTS

One docking wire.

INDICATIONS FOR USE

The Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The Traxcess Docking Wire can be used with Traxcess guidewires to facilitate the placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

There are no known contraindications.

CAUTIONS

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

WARNINGS

The Traxcess Docking Wire 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 Traxcess Docking Wire is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if package is opened or damaged.

The Traxcess Docking Wire 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 Traxcess Docking Wire prior to use for any irregularities or damage and discard if noted.

The Traxcess Docking Wire cannot be used alone and must be used with the guidewire securely connected.

Attachment and detachment to and from the guidewire should be done while confirming the position of the guidewire tip and catheter under high resolution fluoroscopy. The unintentional advancement of the wire may result in perforation or damage to the vasculature or other devices.

Do not bend the Traxcess Docking Wire repeatedly at the same point. This may result in deformation, breakage, or separation of the Traxcess Docking Wire.

Do not torque or manipulate the Traxcess Docking Wire once it is attached. This may cause the Traxcess Docking Wire to detach from the guidewire.

Do not insert the Traxcess Docking Wire into the patient (body). This may result in disconnection or breakage of the Traxcess Docking Wire or damage to the vessel.

PRECAUTIONS

Verify Traxcess Docking Wire compatibility when using other ancillary devices commonly used in intravascular procedure. The physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.

Exercise care in handling the Traxcess Docking Wire to reduce the chance of accidental damage. Do not expose the Traxcess Docking Wire surface to organic solvents such as alcohol or medications, which may damage the coating and/or cause loss of lubricity.

Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the Traxcess Docking Wire is compatible with the outer diameter prior to use.

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.

PREPARATION FOR USE

To prevent damage to the Traxcess Docking Wire, gently remove the wire clip that holds the wire in place in the protective dispenser tube. Gently remove the Traxcess Docking Wire by pulling it from the dispenser tube. Inspect the Traxcess Docking Wire thoroughly to ensure it is not damaged.

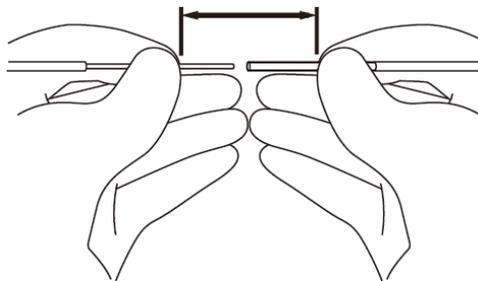
DIRECTIONS FOR USE

Remove any devices, such as a torque device, attached from proximal end of the Traxcess guidewire.

Carefully insert the proximal end of the Traxcess guidewire into the distal end of the Traxcess Docking Wire for connection.

To avoid damage to the Traxcess Docking Wire and guidewire, grip as close to the ends of the wires as possible (Figure 1).

Figure 1



Check for secure attachment by pulling gently both the Traxcess Docking Wire and guidewire on each side of the connection.

Gently open the hemostatic Y-connector attached on the proximal end of the inserted catheter. Withdraw the catheter over the connected wires while maintaining the guidewire tip position.

Introduce the replacement device over the proximal end of the Traxcess Docking Wire. Advance the catheter while maintaining the guidewire tip position.

After placement of the catheter, carefully detach the Traxcess Docking Wire from the guidewire by pulling the Traxcess Docking Wire.

STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the guidewire 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 Traxcess Docking Wire does not contain latex or PVC materials.

SYMBOLS

	Lot Number		Do Not Reuse
	Catalog Number		Use by Date
	Contents		Manufacturer
	Sterilized Using Ethylene Oxide		Authorized European Representative
	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.



Manufacturer:

MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780 USA
Tel: (714) 247-8000
www.microvention.com

Pages 73 through 168 redacted for the following reasons:

-
- (b)(4)-Trade Secret-Draft Labeling, Packaging, Drawings
 - (b)(4)-Trade Secret-Quality Assurance, Risk Management, Test Data/Report



C E R T I F I C A T E

DQS GmbH

Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies that the company

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA 92780
United States of America

for the scope

Design, Development, Manufacturing and Distribution of
Embolization Prostheses and Accessories,
and Intravascular Access Devices and Accessories

has implemented and maintains a

Quality Management System.

An audit, documented in a report, has verified that this
quality management system fulfills the requirements
of the following standard:

EN ISO 13485 : 2003 + AC: 2007

October 2007 edition

This certificate is valid until 2013-11-20

Certificate Registration No. 411133 MP27

Frankfurt am Main 2009-07-21

Ass. iur. M. Drechsel

MANAGING DIRECTORS

Dipl.-Bw. J. Böge



D-60433 Frankfurt am Main, August-Schanz-Straße 21



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-ZQ-987.99.07-46



EC - CERTIFICATE

DQS GmbH

Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies that the company

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA 92780
United States of America

has implemented and maintains a

Quality Management System.

An audit, documented in a report, performed by DQS
has verified that this quality management system
fulfills the requirements of

Annex II of Directive 93/42/EEC

with respect to the following medical devices:

as listed in the annex

As set out in section 5, Annex II, of the said directive, the manufacturer of these devices is subject to surveillance.
The CE-mark with the number of the notified body may be used on the devices listed in the certificate.

CE 0297

This certificate is valid until 2011-10-29

Certificate Registration No. 411133 MR2

Frankfurt am Main 2009-07-21

Ass. iur. M. Drechsel

MANAGING DIRECTORS

Dipl.-Bw. J. Böge

D-60433 Frankfurt am Main, August-Schanz-Straße 21



**Annex to Certificate Registration No.: 411133 MR2
Issued: 2009-07-21**

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA 92780
United States of America

Products:

Product Groups:	Product Family	Products:	Risk Class
Embolization Prostheses	Detachable Embolization Coils with HydroLink® Detachment System	MicroPlex® Platinum Detachable Embolization Coils - Helical – Helical-Reg. and Soft 10 & 18 - HyperSoft™ 10 - Complex 1D 10 & 18	III
		HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - Helical 10 & 14 & 18	
	V-Trak® Detachable Embolization Coils System	MicroPlex® Platinum Detachable Embolization Coils - Helical - Standard Helical-Reg. and Soft 10 & 18, - HyperSoft™ 10 - Complex - Complex 10 & 18, Compass 10 & 18, - COSMOS 10 - COSMOS 18	III
		HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - HydroCoil® 10 & 14 & 18, HydroSoft™ 10, HydroSoft™ Plus 10 - HydroFrame - HydroFill 10 (HES) - Berenstein HydroFlow 10 & 18	
	AZUR™ Peripheral HydroCoil® Embolization Coil System	AZUR™ HydroCoil Detachable Embolization Coils 18 AZUR™ HydroCoil Pushable Embolization Coils 18 & 35	IIb
Detachment Controller Units		V-Grip™ Detachment Controller V-Grip™ PLUS Detachment Controller	IIa
		AZUR™ Detachment Controller	IIa
Intravascular Access Devices		Traxcess™ Guidewires	III
Catheters		Chaperon Guiding Catheter System Headway 17 Microcatheter	III

This annex (issued: 2009-08-18) is only valid in connection
with the above mentioned certificate.

Confidential

Page 155 of 158

Pages 172 through 174 redacted for the following reasons:

(b)(4)-Trade Secret-Contract Manufacturer Information



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

COVER SHEET MEMORANDUM

From: Reviewer Name Nicole Ibrahim
Subject: 510(k) Number K093597/S
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/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/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		✓	
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		✓	✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

4

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	✓

Regulation Number Class* Product Code

21 CFR 870.130 DQX

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

Additional Product Codes: _____

Review: _____

(Branch Chief) PVDB 12/17/09

(Branch Code) (Date)

Final Review: _____

(Division Director) _____ 12/17/09

(Date)

5

SPECIAL 510(k): Device Modification

ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

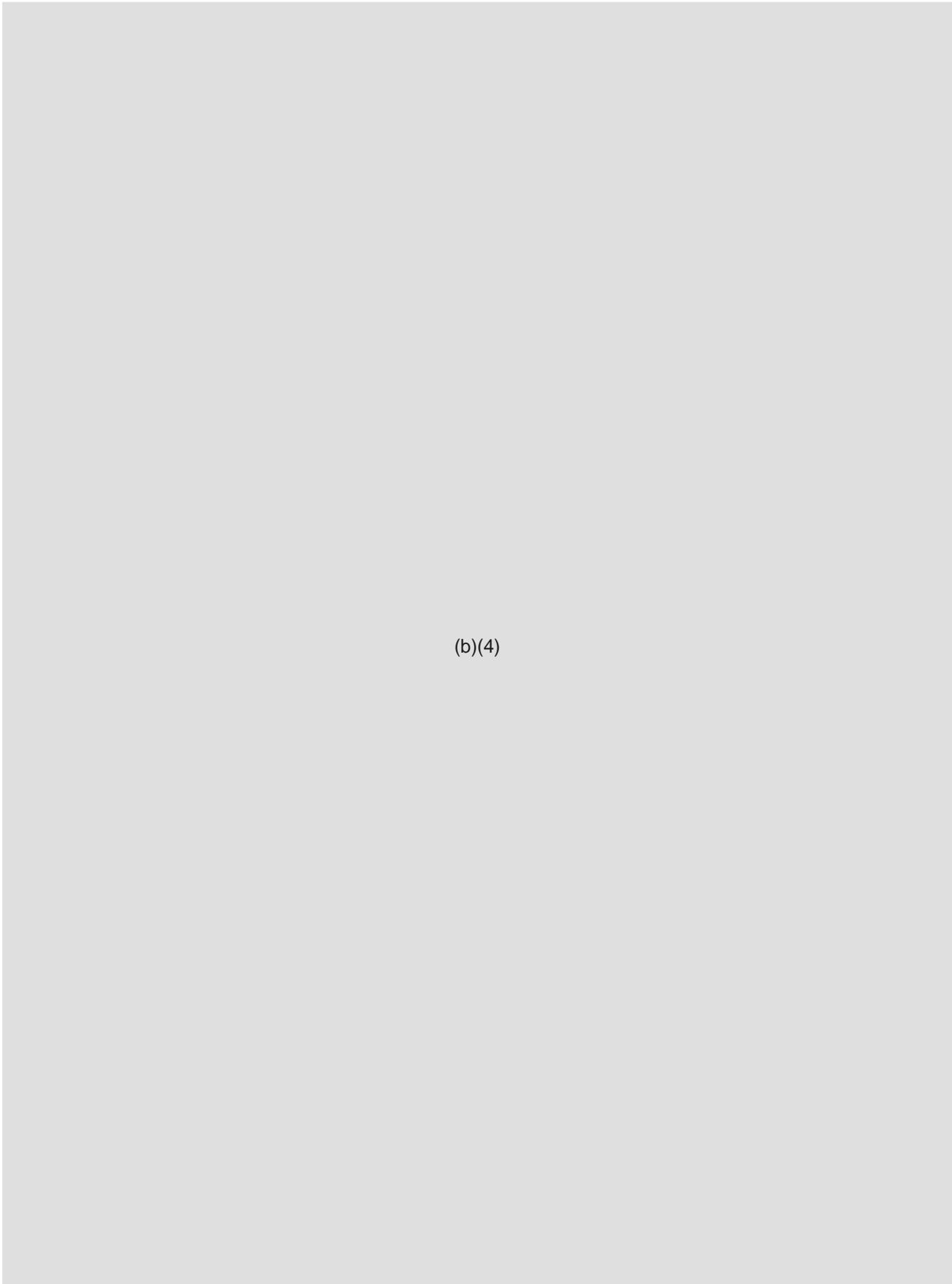
RE: DOCUMENT NUMBER K093397

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(b)(4)

2



(b)(4)

9

Pg 25

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

Truthful and Accurate Statement: pg 12

510(k) Summary: pg 14

Indications for Use: pg 17

Michelle D. H. H.
(Reviewer's Signature)

12-17-09
(Date)

Comments H/C 12/17/09

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

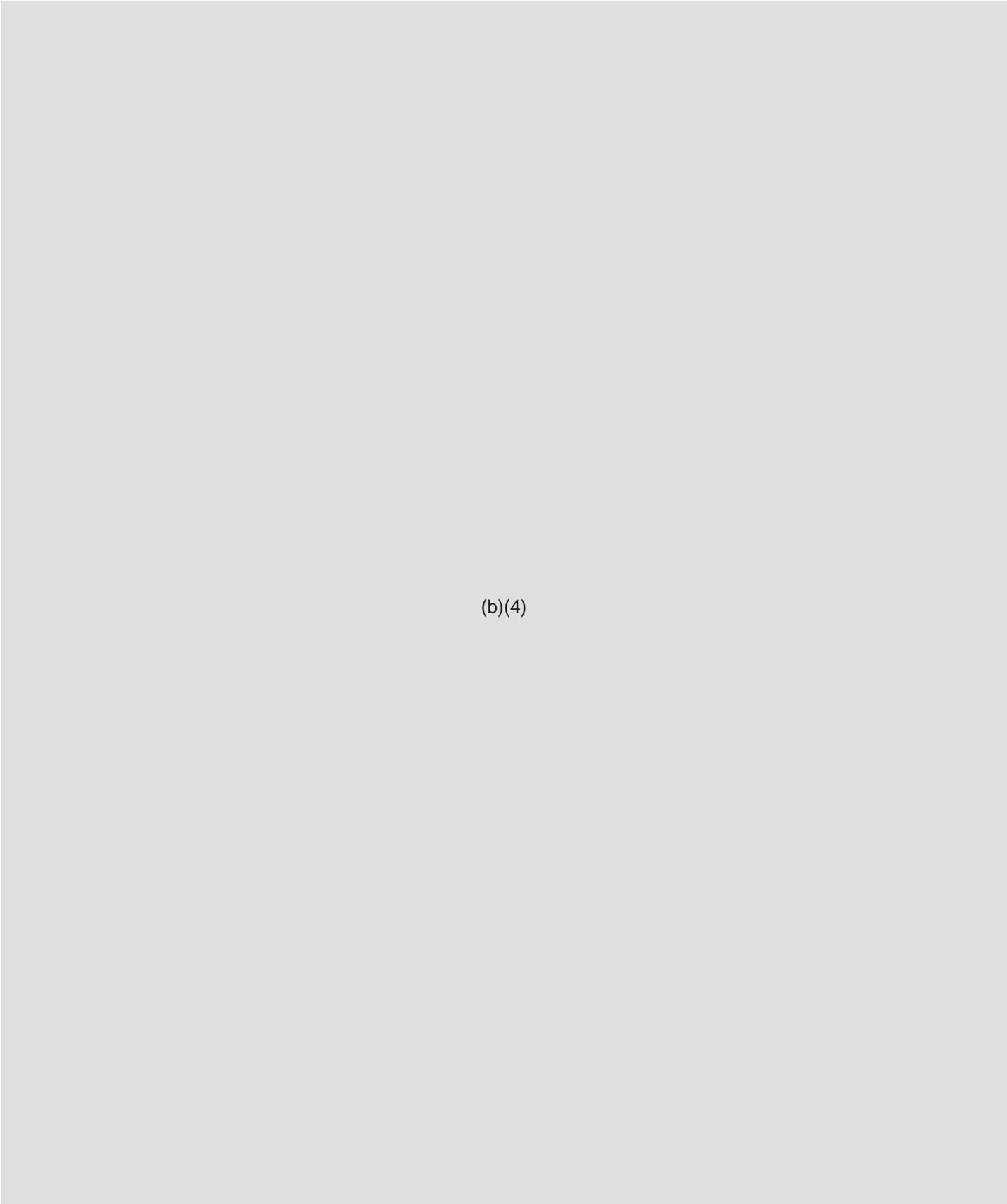
http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:

10

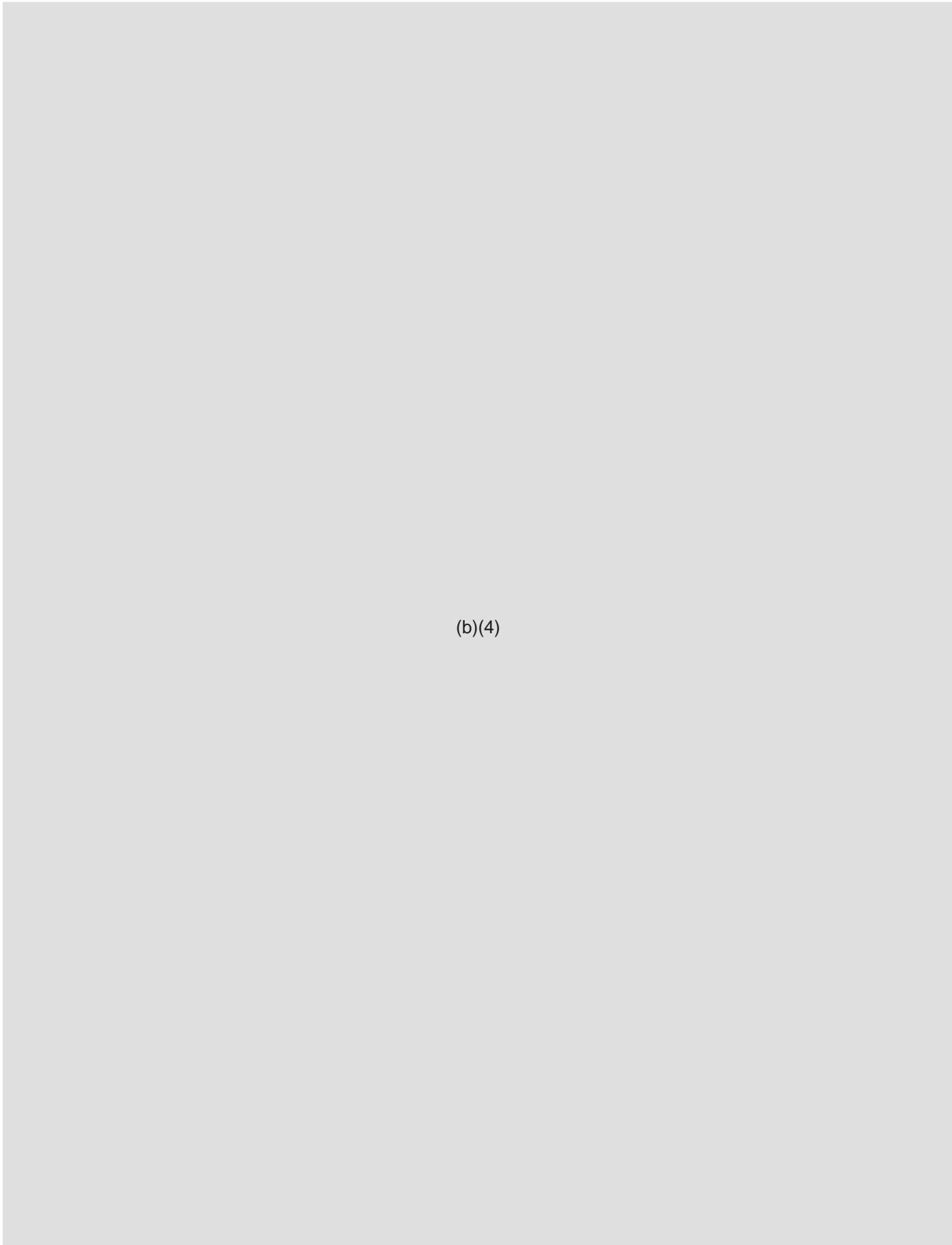
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough: (b)(4)
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: (b)(4)
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4)



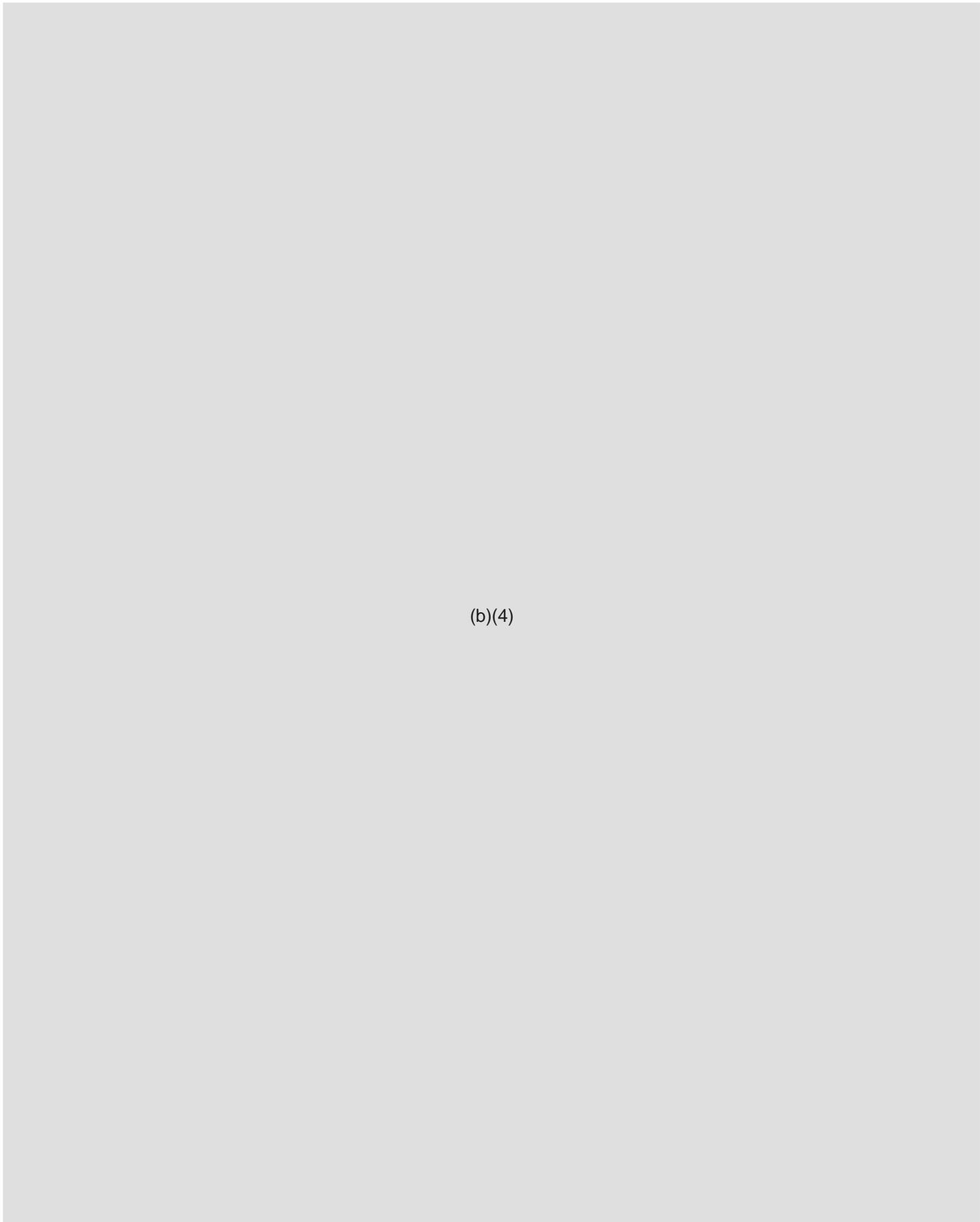
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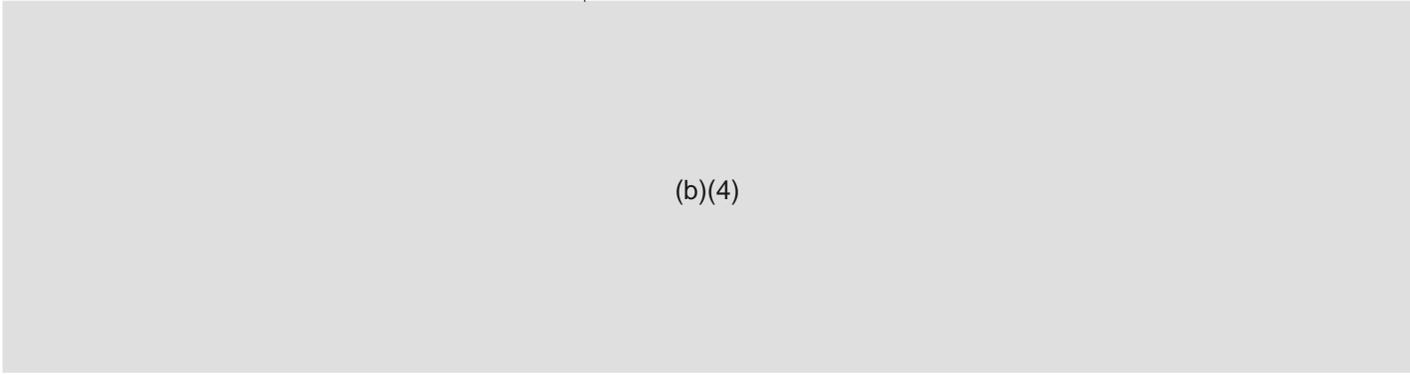
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(b)(4)

14



(b)(4)

15



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Devices & Radiological Health

Division of Ophthalmic, Neurology, and ENT Devices
Neurodiagnostic and Neurotherapeutic Devices Branch
WO66, Room 2454
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review

K093397/S1

Date: Original: 11-18-09
Supplement 1: 12-15-09

To: Nicole Ibrahim, Ph.D. (Lead Reviewer, DCD/ICDB)
The File

From: Kristen A. Bowsher, Ph.D.
Biomedical and Electrical Engineer
ODE/DONED/NNDB

Device Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

510(k) Holder: MicroVention

RECOMMENDATION

(b)(4)

16

Table of Contents

I.	Purpose and Submission Summary	3
II.	Review Scope	3
III.	Indications for Use	3
IV.	Device Description	3
V.	Comparison to Predicate Devices	4
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	A. Traxcess 14EX	6
	B. Traxcess Docking Wire	8
VII.	(b)(4)	12
VIII.	Recommendation	13

17

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Traxcess 14EX Guidewire and Traxcess Docking Wire into interstate commerce. The device is classified as follows: Catheter guidewire, 21 CFR 870.1330, Class II, product code DQX.

II. Review Scope

This review will cover the engineering aspects of the device.

III. Indications for Use

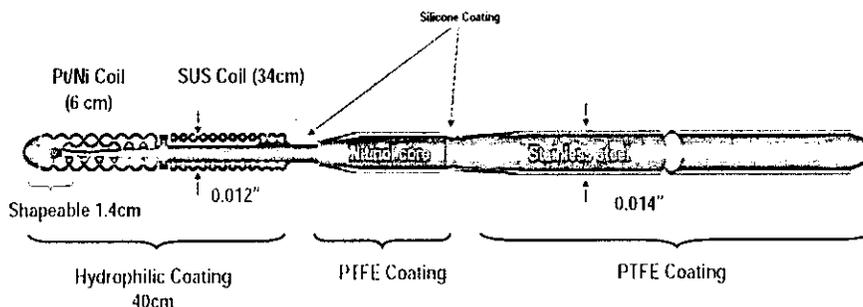
As specified in the "Indications for Use" form:

"The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries."

IV. Device Description

Traxcess 14EX

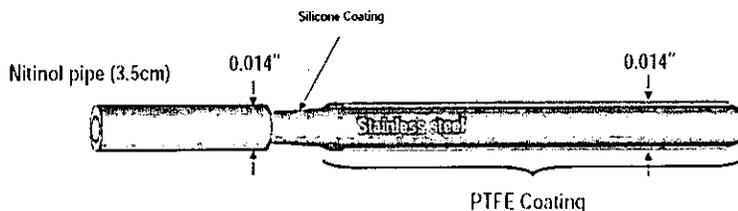
The Traxcess 14EX consists of a proximal 0.014" diameter stainless steel shaft and a distal tapered nitinol wire contained within 0.012" diameter platinum and stainless steel coils. The distal coil surface is coated with a lubricious hydrophilic coating and the proximal shaft section is coated with PTFE/silicone. The proximal end is tapered in order to connect to the Traxcess Docking Wire. The distal 14 mm of the guidewire is shapeable by the physician. A shaping mandrel, inserter, and torque device are included with the device.



Traxcess 14EX

Traxcess Docking Wire

The Traxcess Docking Wire is an accessory used to extend the overall length of the Traxcess guidewire for facilitating catheter replacement. To extend the guidewire length, the proximal end of the Traxcess guidewire is connected to the Traxcess Docking Wire. The Traxcess Docking Wire is removed when it is not needed. The Traxcess Docking Wire consists of a proximal stainless steel shaft and nitinol pipe (tube) attached at the distal end (diameter of 0.014"). The proximal shaft is coated with PTFE and silicone for lubricity. The Traxcess Docking Wire is provided sterile and sold separately.



Traxcess Docking Wire

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Dimensions of Traxcess 14EX and Traxcess Docking Wire

Device	Catalogue Number	Length	Distal Length (Shapeable)	Size (Prox/distal)
Traxcess 14EX	GW1420040X	200 cm	14 mm	0.014"/0.012"
Traxcess Docking Wire	GW14100EX	115 cm	N/A	0.014"

Reviewer Comments

The device description is adequate.

V. Comparison to Predicate Devices**Traxcess 14EX Guidewire**

The sponsor states that the Traxcess 14EX Guidewire is substantially equivalent to the predicate, **Traxcess 14 Guidewire [aka Traxcess 0.014' Hydrophilic Guidewire] (K080863)** in terms of design, construction of materials, and function. They are both made of the same materials and coated with the same hydrophilic and PTFE/silicone coatings.

The sponsor states that the Traxcess 14EX has maintained the same fundamental technological design as the predicate Traxcess 14. The differences between the two devices involve only the distal tip segment of the guidewire and are summarized below:

- Distal tip thickness of the core wire has been increased from 0.037 mm to 0.058 mm.
- Radiopaque (Pt/Ni) segment has been lengthened to 6 cm from 3 cm.
- Proximal end has been configured to be compatible with the Traxcess Docking Wire.
Addition of the Traxcess Docking Wire as an accessory to the device.

The table on the next page provides a comparison of the proposed Traxcess 14EX and the predicate device:

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Prefix: Traxcess 14 (K080463)		Traxcess 14EX
Guidewire Attributes		
Intended Use	The Traxcess 14 Guidewire is intended for general intravascular use, including the neck and peripheral vasculature. The wire can be created to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.	Same
Diameter	Proximal = 0.014" Distal = 0.012"	Same
Overall Length	200 cm	Same
Distal Shaft Length (Shapeable Length)	1.4 cm	Same
Material	Core wire (proximal): Stainless steel Core wire (distal): Nickel titanium alloy Coil: Stainless steel and Platinum nickel alloy Other: Brazing material and solder	Same
Coating	Shaft: PTFE/silicone Coil: Hydrophilic Coating (dimethylacamide-glycidyl methacrylate copolymer)	Same
Coil Length	40 cm	Same
Radiopaque Length	3 cm	6 cm
Distal tip thickness (core wire)	0.057 mm	0.058 mm
Proximal end configuration	Straight	Tapered to be compatible with Traxcess docking wire
Other attributes		
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Accessories	Shaping mandrel, torque device, and Insertor	Same
Package configuration	Placed into a dispenser hoop, tyvek pouch, and box carton.	Same

Traxcess Docking Wire

The sponsor states that the Traxcess Docking Wire is substantially equivalent to the predicate, **Terumo Runthrough NS Extension Wire (K080563)**. The Traxcess Docking Wire is identical to the Terumo Runthrough NS Extension Wire except that it is shorter in length. MicroVention-Terumo is a wholly owned subsidiary of Terumo Medical Corporation (Elkton, MD). The following is a comparison table:

Prefix: Runthrough NS Extension Wire (K080563)		Traxcess Docking Wire
Guidewire Attributes		
Outer Diameter (OD)	0.014"	Same
Overall Length	120-165 cm	115 cm
Pipe Length	2-7 cm	3.5 cm
Material	Shaft: Stainless steel Pipe: Nickel titanium alloy Other: Brazing material and solder	Same
Coating	PTFE Silicone	Same
Other attributes		
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Package configuration	Placed into a dispenser hoop, tyvek pouch, and box carton.	Same

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Reviewer Comments

The sponsor has chosen appropriate predicate devices and provided an adequate comparison of the technical features of the devices. See Section VI for a comparison of the performance testing.

VI. Performance Testing

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met

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(b)(4)

(b)(4)

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MEMORANDUM

Date: December 16, 2009

From: Jeffrey Toy, Ph.D., Toxicologist

Subject: K093397/S001 –MicroVention Traxcess 14ex Guidewire and Traxcess Docking Wire Animal Study Review

To: The Record

Through: Nicole Ibrahim
Team Leader (DCD)

RECOMMENDATION: SUBSTANTIALLY EQUIVALENT

PURPOSE

MicroVention submits a 510k to introduce into Traxcess 14ex Guidewire and Traxcess Docking Wire interstate commerce.

IN MY DISCUSSION WITH NICOLE, SHE REQUESTED I PROVIDE A NEUROLOGICAL PERSPECTIVE ON THE ANIMAL STUDY ONLY. I will not address any material biocompatibility issue.

INDICATION FOR USE

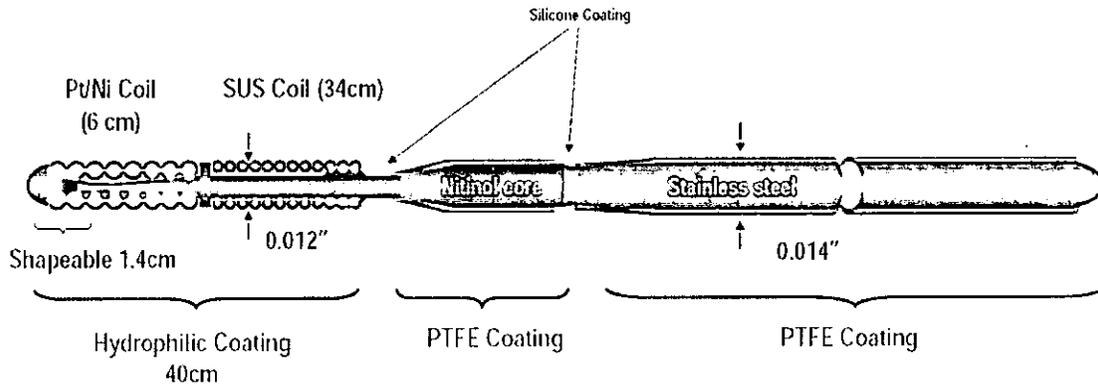
The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

BACKGROUND

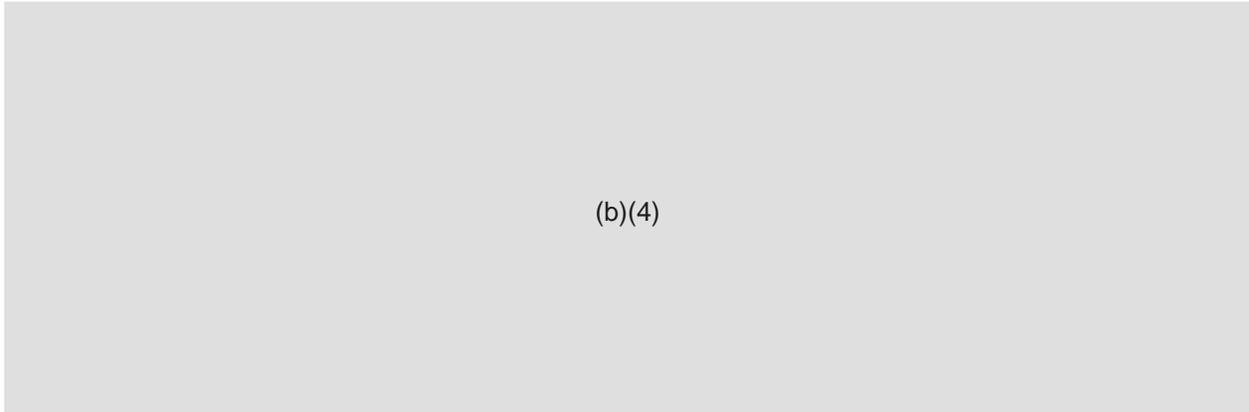
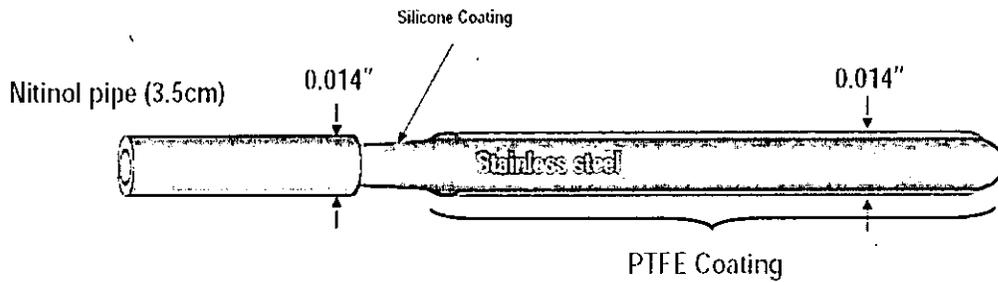
The MicroVention-Terumo Traxcess 14EX Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

The Traxcess 14EX consists of a proximal 0.014" diameter stainless steel shaft and a distal tapered nitinol wire contained within 0.012" diameter platinum and stainless steel coils. The distal coil surface is coated with a lubricious hydrophilic coating and the proximal shaft section is coated with PTFE/silicone. The proximal end is tapered in order to connect to the Traxcess Docking Wire. The distal 14 mm of the guidewire is shapeable by the physician. A shaping mandrel, inserter, and torque device are included with the device. A picture of the Traxcess 14EX guidewire is provided below.

K093397/S001 – Animal Study

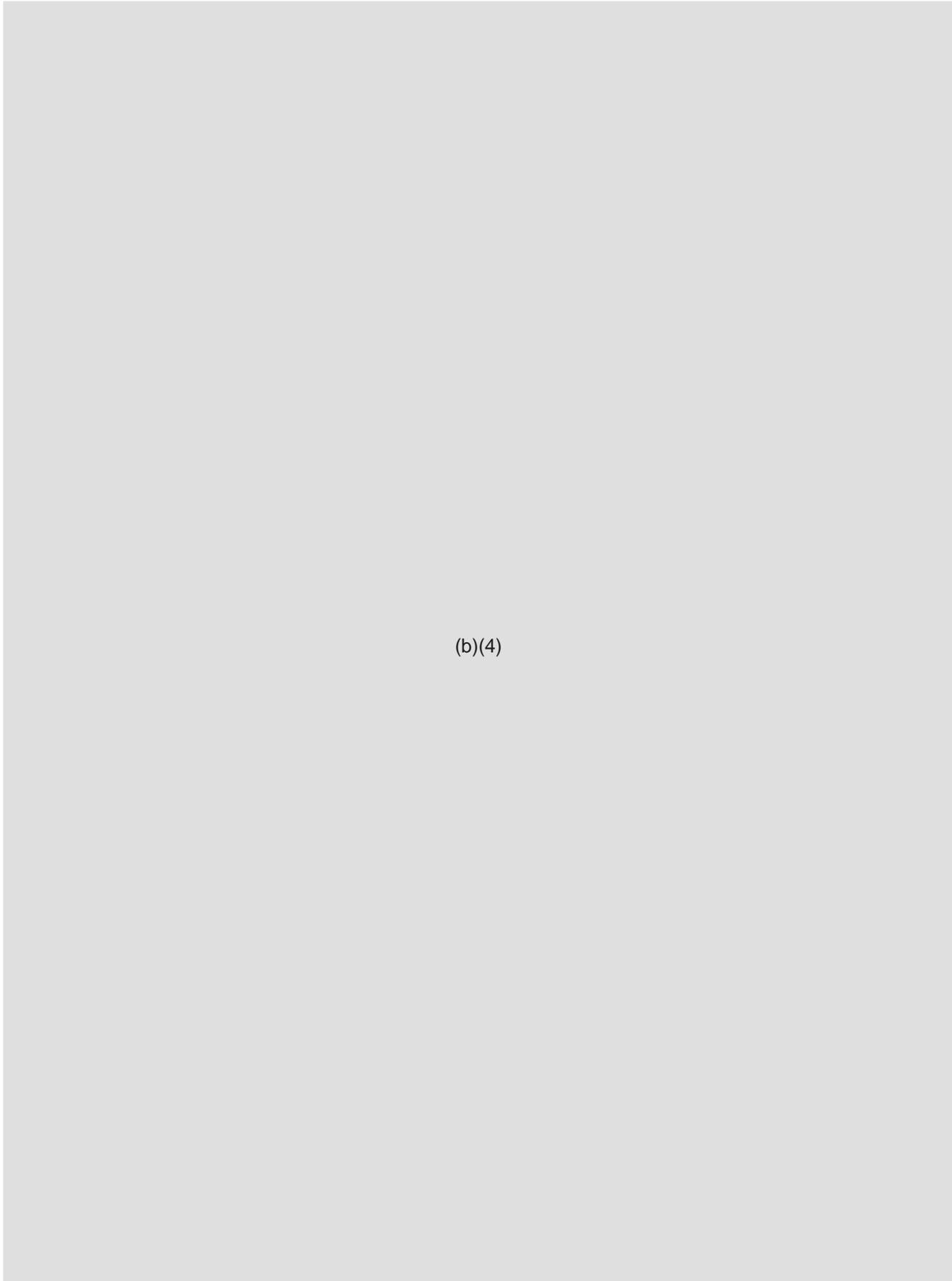


The Traxcess Docking Wire is an accessory used to extend the overall length of the Traxcess guidewire for facilitating catheter replacement. To extend the guidewire length, the proximal end of the Traxcess guidewire is connected to the Traxcess Docking Wire. The Traxcess Docking Wire is removed when it is not needed. The Traxcess Docking Wire consists of a proximal stainless steel shaft and nitinol pipe (tube) attached at the distal end (diameter of 0.014"). The proximal shaft is coated with PTFE and silicone for lubricity. The Traxcess Docking Wire is provided sterile and sold separately. A picture of the Traxcess docking wire is provided below:



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K093397/S001 – Animal Study



(b)(4)

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K093397/S001 – Animal Study

(b)(4)

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COVER SHEET MEMORANDUM

From: Reviewer Name Nicde Ibrahim
Subject: 510(k)-Number K093397
To: The Record

- Please list CTS decision code AI
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

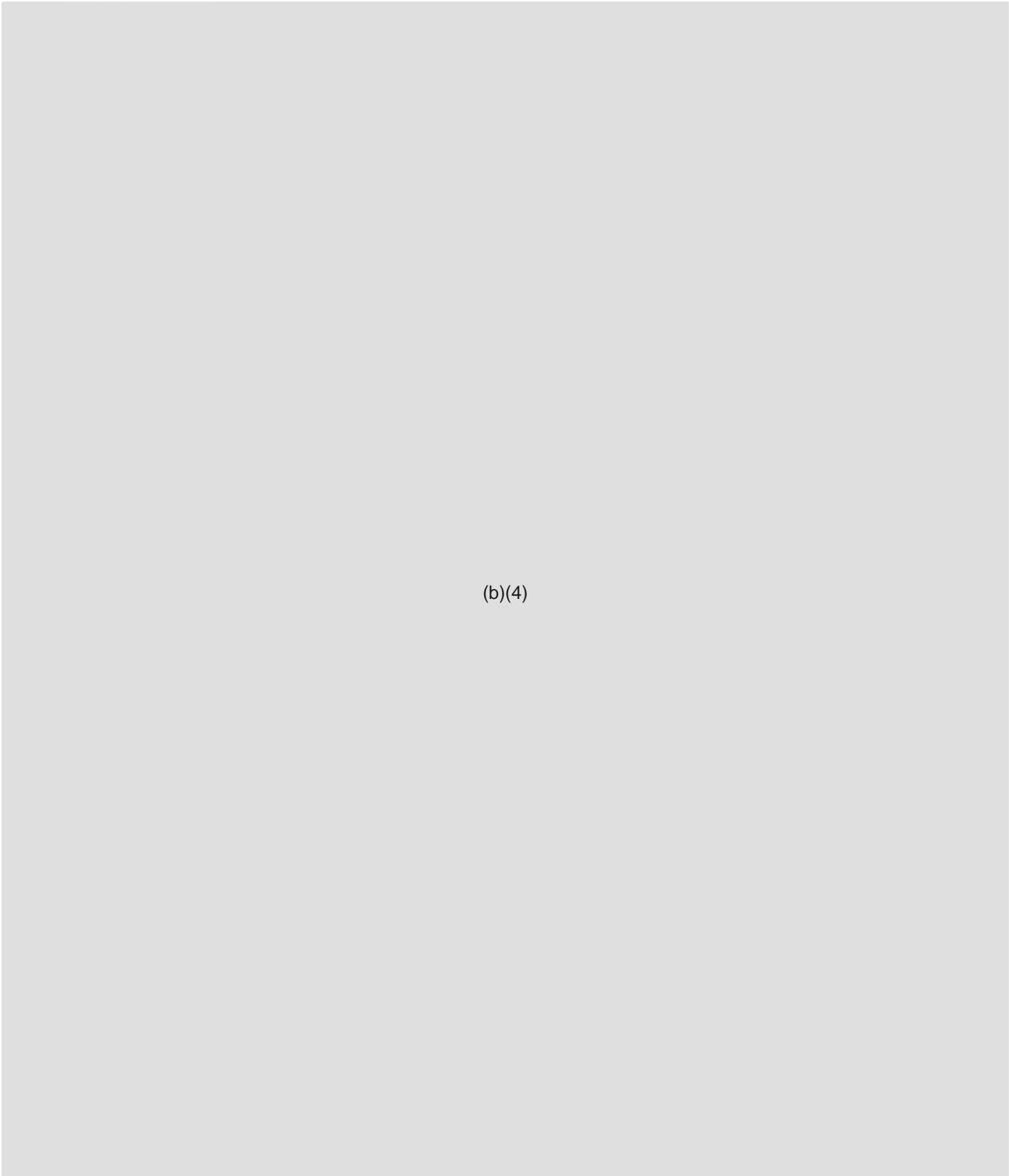
Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III? If yes, 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/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.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

SPECIAL 510(k): Device Modification

ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K093397



(b)(4)

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(b)(4)

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Pg 25

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

Truthful and Accurate Statement: pg 12

510(k) Summary: pg 14

Indications for Use: pg 17

Nicole D. H...

(Reviewer's Signature)

11/24/09

(Date)

Comments

K/C

11/24/09

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		X	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:

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4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough: (b)(4)
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: (b)(4)
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Devices & Radiological Health

Division of Ophthalmic, Neurology, and ENT Devices
Neurodiagnostic and Neurotherapeutic Devices Branch
WO66, Room 2454
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review

K093397

Date: 11-18-09

To: Nicole Ibrahim, Ph.D. (Lead Reviewer, DCD/ICDB)
The File

From: Kristen A. Bowsher, Ph.D.
Biomedical and Electrical Engineer
ODE/DONED/NNDB

Device Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

510(k) Holder: MicroVention

(b)(4)

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Table of Contents

I.	Purpose and Submission Summary	3
II.	Review Scope	3
III.	Indications for Use	3
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V.	Comparison to Predicate Devices	4
VI.	Performance Testing	6
	A. Traxcess 14EX	6
	B. Traxcess Docking Wire	8
VII.	(b)(4)	12
VIII.	Recommendation	12

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I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Traxcess 14EX Guidewire and Traxcess Docking Wire into interstate commerce. The device is classified as follows: Catheter guidewire, 21 CFR 870.1330, Class II, product code DQX.

II. Review Scope

This review will cover the engineering aspects of the device.

III. Indications for Use

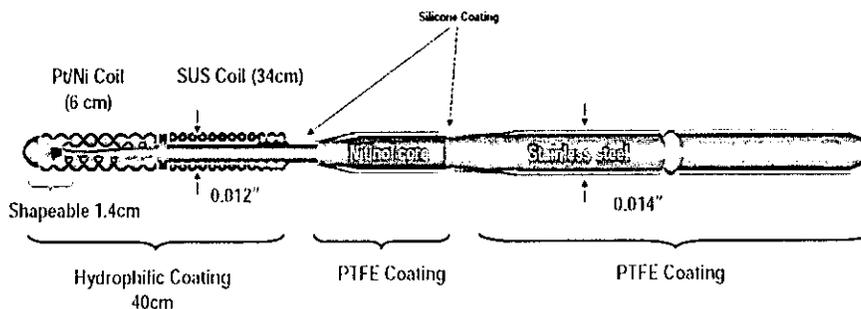
As specified in the "Indications for Use" form:

"The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries."

IV. Device Description

Traxcess 14EX

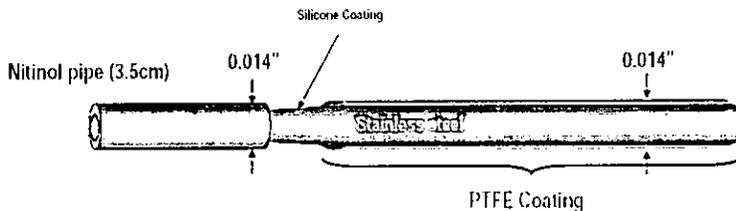
The Traxcess 14EX consists of a proximal 0.014" diameter stainless steel shaft and a distal tapered nitinol wire contained within 0.012" diameter platinum and stainless steel coils. The distal coil surface is coated with a lubricious hydrophilic coating and the proximal shaft section is coated with PTFE/silicone. The proximal end is tapered in order to connect to the Traxcess Docking Wire. The distal 14 mm of the guidewire is shapeable by the physician. A shaping mandrel, inserter, and torque device are included with the device.



Traxcess 14EX

Traxcess Docking Wire

The Traxcess Docking Wire is an accessory used to extend the overall length of the Traxcess guidewire for facilitating catheter replacement. To extend the guidewire length, the proximal end of the Traxcess guidewire is connected to the Traxcess Docking Wire. The Traxcess Docking Wire is removed when it is not needed. The Traxcess Docking Wire consists of a proximal stainless steel shaft and nitinol pipe (tube) attached at the distal end (diameter of 0.014"). The proximal shaft is coated with PTFE and silicone for lubricity. The Traxcess Docking Wire is provided sterile and sold separately.



Traxcess Docking Wire

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Dimensions of Traxcess 14EX and Traxcess Docking Wire

Device	Catalogue Number	Length	Distal Length (Shapeable)	Size (Prox/distal)
Traxcess 14EX	GW1420040X	200 cm	14 mm	0.014"/0.012"
Traxcess Docking Wire	GW14100EX	115 cm	N/A	0.014"

Reviewer Comments

The device description is adequate.

V. Comparison to Predicate Devices**Traxcess 14EX Guidewire**

The sponsor states that the Traxcess 14EX Guidewire is substantially equivalent to the predicate, **Traxcess 14 Guidewire [aka Traxcess 0.014' Hydrophilic Guidewire] (K080863)** in terms of design, construction of materials, and function. They are both made of the same materials and coated with the same hydrophilic and PTFE/silicone coatings.

The sponsor states that the Traxcess 14EX has maintained the same fundamental technological design as the predicate Traxcess 14. The differences between the two devices involve only the distal tip segment of the guidewire and are summarized below:

- Distal tip thickness of the core wire has been increased from 0.037 mm to 0.058 mm.
- Radiopaque (Pt/Ni) segment has been lengthened to 6 cm from 3 cm.
- Proximal end has been configured to be compatible with the Traxcess Docking Wire.
Addition of the Traxcess Docking Wire as an accessory to the device.

The table on the next page provides a comparison of the proposed Traxcess 14EX and the predicate device:

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Existing Terumo 14 (K08063)		Traxcess 14EX
Guidewire Attributes		
Intended Use	The Traxcess 14 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be created to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.	Same
Diameter	Proximal = 0.014" Distal = 0.012"	Same
Overall Length	200 cm	Same
Distal Shaft Length (Shapeable Length)	1.4 cm	Same
Material	Core wire (proximal): Stainless steel Core wire (distal): Nickel titanium alloy Coil: Stainless steel and Platinum nickel alloy Other: Brazing material and solder	Same
Coating	Shaft: PTFE/silicone Coil: Hydrophilic Coating (dimethylacrylamide-glycidyl methacrylate copolymer)	Same
Coil Length	46 cm	Same
Radiopaque Length	3 cm	6 cm
Distal tip thickness (core wire)	0.037 mm	0.058 mm
Proximal end configuration	Straight	Tapered to be compatible with Traxcess docking wire
Other attributes		
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Accessories	Shaping mandrel, torque device, and Insertion	Same
Package configuration	Placed into a dispenser hoop, Tyvek pouch, and box carton.	Same

Traxcess Docking Wire

The sponsor states that the Traxcess Docking Wire is substantially equivalent to the predicate, **Terumo Runthrough NS Extension Wire (K080563)**. The Traxcess Docking Wire is identical to the Terumo Runthrough NS Extension Wire except that it is shorter in length. MicroVention-Terumo is a wholly owned subsidiary of Terumo Medical Corporation (Elkton, MD). The following is a comparison table:

Existing Runthrough NS Extension Wire (K080563)		Traxcess Docking Wire
Guidewire Attributes		
Outer Diameter (OD)	0.014"	Same
Overall Length	120-165 cm	115 cm
Pipe Length	2-7 cm	3.5 cm
Material	Shaft: Stainless steel Pipe: Nickel titanium alloy Other: Brazing material and solder	Same
Coating	PTFE Silicone	Same
Other attributes		
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Package configuration	Placed into a dispenser hoop, Tyvek pouch, and box carton.	Same

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Reviewer Comments

The sponsor has chosen appropriate predicate devices and provided an adequate comparison of the technical features of the devices. See Section VI for a comparison of the performance testing.

VI. Performance Testing

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See also reviewer comments in Section VI regarding the poor performance of the predicate device in the simulated use model.

MEMORANDUM

Date: November 19, 2009

From: Jeffrey Toy, Ph.D., Toxicologist

Subject: K093397 –MicroVention Traxcess 14ex Guidewire and Traxcess Docking Wire Animal Study Review

To: The Record

Through: Nicole Ibrahim
Team Leader (DCD)

RECOMMENDATION: ADDITIONAL INFORMATION

PURPOSE

MicroVention submits a 510k to introduce into Traxcess 14ex Guidewire and Traxcess Docking Wire interstate commerce.

IN MY DISCUSSION WITH NICOLE, SHE REQUESTED I PROVIDE A NEUROLOGICAL PERSPECTIVE ON THE ANIMAL STUDY ONLY. I will not address any material biocompatibility issue.

INDICATION FOR USE

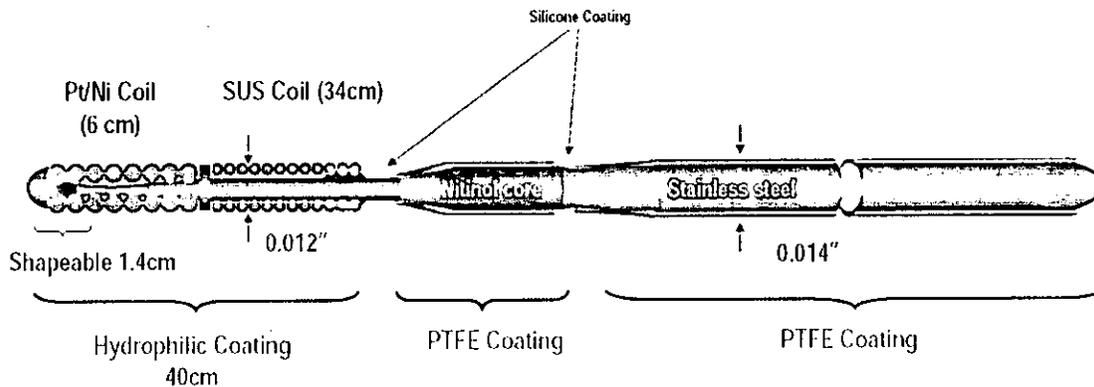
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BACKGROUND

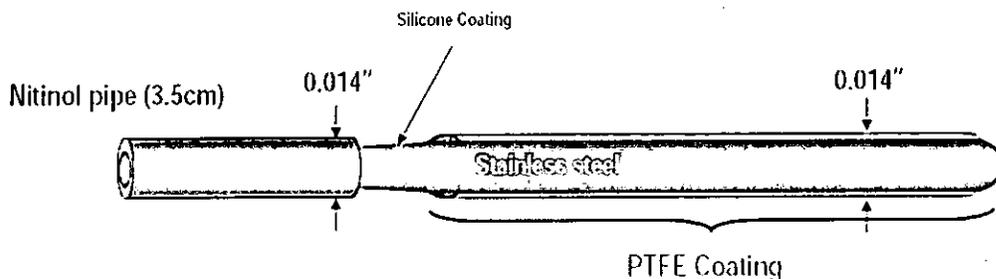
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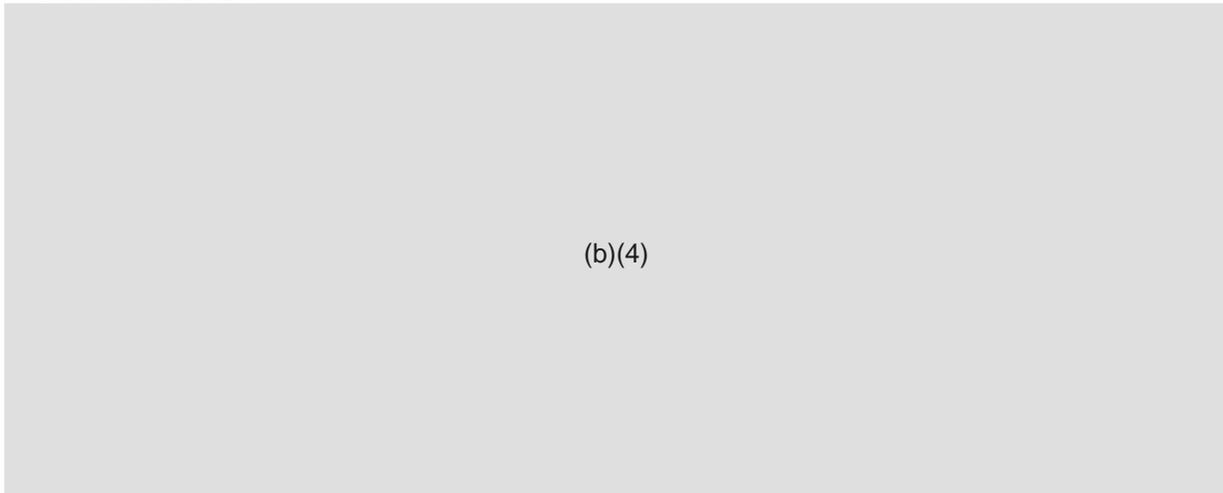
K093397 – Animal Study



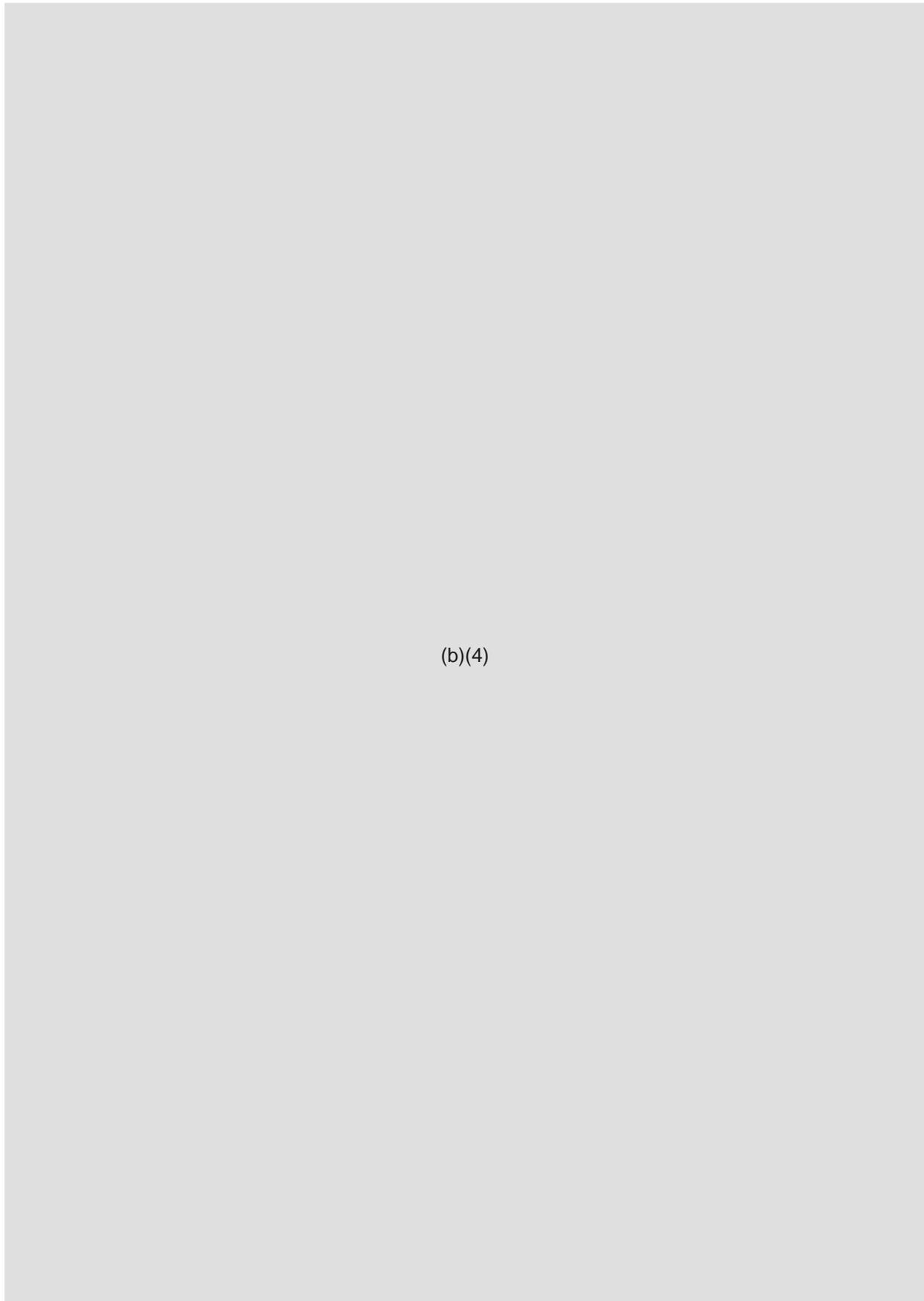
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ANIMAL STUDY



K093397 – Animal Study



(b)(4)

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K093397 – Animal Study

(b)(4)

9/5

Hampshire, Victoria

From: Hampshire, Victoria
Sent: Friday, November 06, 2009 10:47 AM
To: Ibrahim, Nicole
Subject: informal review of K093397

WAA

Hello Nicole:

(b)(4)

Tory

Victoria Hampshire, VMD
Senior Regulatory Veterinarian and Reviewer
US Food and Drug Administration
Center for Devices and Radiologic Health
Office of Device Evaluation
Division of Cardiovascular Devices
10903 New Hampshire Avenue
Room 1218
Silver Spring, MD 20993
Phone 301-796-6375
e-mail: Victoria.Hampshire@fda.hhs.gov

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Ibrahim, Nicole

From: Gong Naomi [Naomi.Gong@microvention.com]
Sent: Monday, November 23, 2009 4:23 PM
To: Ibrahim, Nicole
Subject: 510(k) submission K093397

Dear Nicole:

(b)(4)

Thank you and please let me know if you have any additional questions.

Regards,

Naomi Gong
Regulatory Affairs Project Manager
MicroVention, Inc.
714-247-8055
naomi.gong@microvention.com

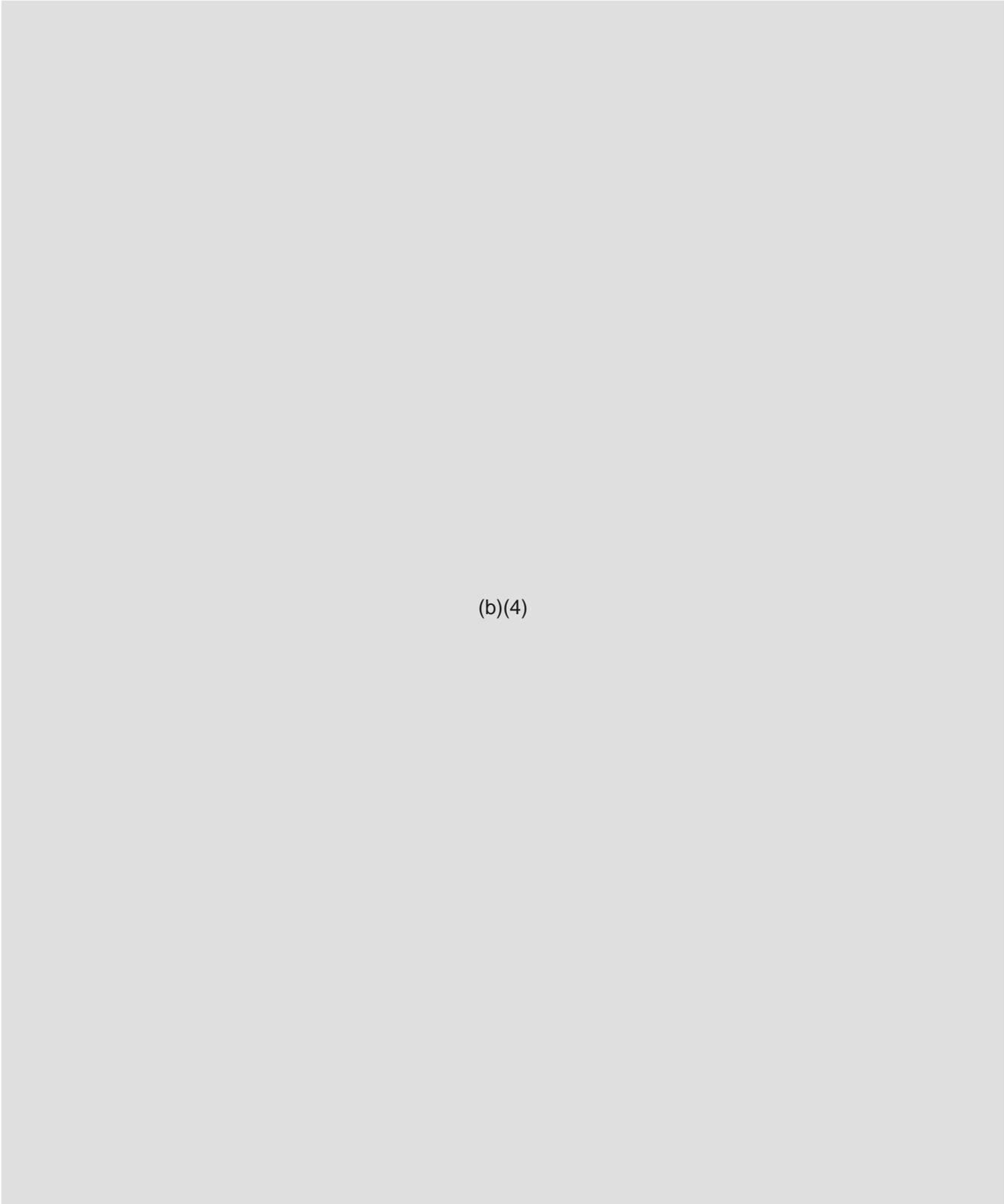
CONFIDENTIALITY NOTICE: This email contains information from the sender that may be confidential, legally privileged, proprietary or otherwise protected from disclosure. This email is intended for use only by the person or entity to whom it is addressed. If you are not the intended recipient, any use, disclosure, copying, distribution, printing, or any action taken in reliance on the contents of this email, is strictly prohibited. If you received this email in error, please contact the sending party by replying in an email to the sender, delete the email from your computer system and destroy any paper copies of the printed email.

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11/23/2009

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

510(k) "SUBSTANTIAL EQUIVALENCE"



(b)(4)

- ❖ 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 14, 2009

MICROVENTION, INC.
1311 VALENCIA AVE
TUSTIN, CALIFORNIA 92780
UNITED STATES
ATTN: NAOMI GONG

510k Number: K093397

Product: TRAXCESS 14EX GUIDEWIRE AND TR

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

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

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

Sincerely,

510(k) Staff

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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
 12/11/2009

User Fee Payment ID Number
 (b)(4)

FDA Submission Document Number (if known)
 K093397 / 9

SECTION A TYPE OF SUBMISSION

<p>PMA</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p>PMA & HDE Supplement</p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p>510(k)</p> <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p>Meeting</p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Other Submission</p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 MicroVention, Inc.		Establishment Registration Number (if known) 2032493	
Division Name (if applicable)		Phone Number (including area code) (714) 247-8055	
Street Address 1311 Valencia Avenue		FAX Number (including area code) (949) 247-8014	
City Tustin	State / Province CA	ZIP/Postal Code 92780	Country USA
Contact Name Naomi Gong			
Contact Title Regulatory Affairs Project Manager		Contact E-mail Address naomi.gong@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		
<input type="checkbox"/> Withdrawal <input checked="" type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Reponse to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (specify): Additional models in the Traxcess Guidewire family		

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	DQX	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K080863	1	Traxcess 14 Guidewire	1	Microvention, Inc. 1311 Valencia Avenue Tustin, California, 92780
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
Catheter guidewire

	Trade or Proprietary or Model Name for This Device		Model Number
1	Traxcess 14EX Guidewire	1	GW1420040X
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 DQX	C.F.R. Section (if applicable) 21 CFR 870.1330	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Cardiovascular Devices		

Indications (from labeling)
Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

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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			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number 2032493	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name MicroVention, Inc. (Terumo)		Establishment Registration Number 2032493	
Division Name (if applicable)		Phone Number (including area code) (714) 247-8055	
Street Address 1311 Valencia Avenue		FAX Number (including area code) (714) 247-8014	
City Tustin	State / Province CA	ZIP/Postal Code 92780	Country USA
Contact Name Naomi Gong	Contact Title Regulatory Affairs Project Manager	Contact E-mail Address naomi.gong@microvention.com	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> 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	
(b)(4)			

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					
2					
3					
4					
5					
6					
7					

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

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K093397/S



December 11, 2009

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

RE: Response to Request for Additional Information
510(k) No. K093397 Traxcess 14EX Guidewire

Dear Dr. Ibrahim:

(b)(4)

Included in this submission are the CDRH Cover Sheet and a second copy of this letter and accompanying documentation.

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 response. Please contact me if you have any questions.

Respectfully,

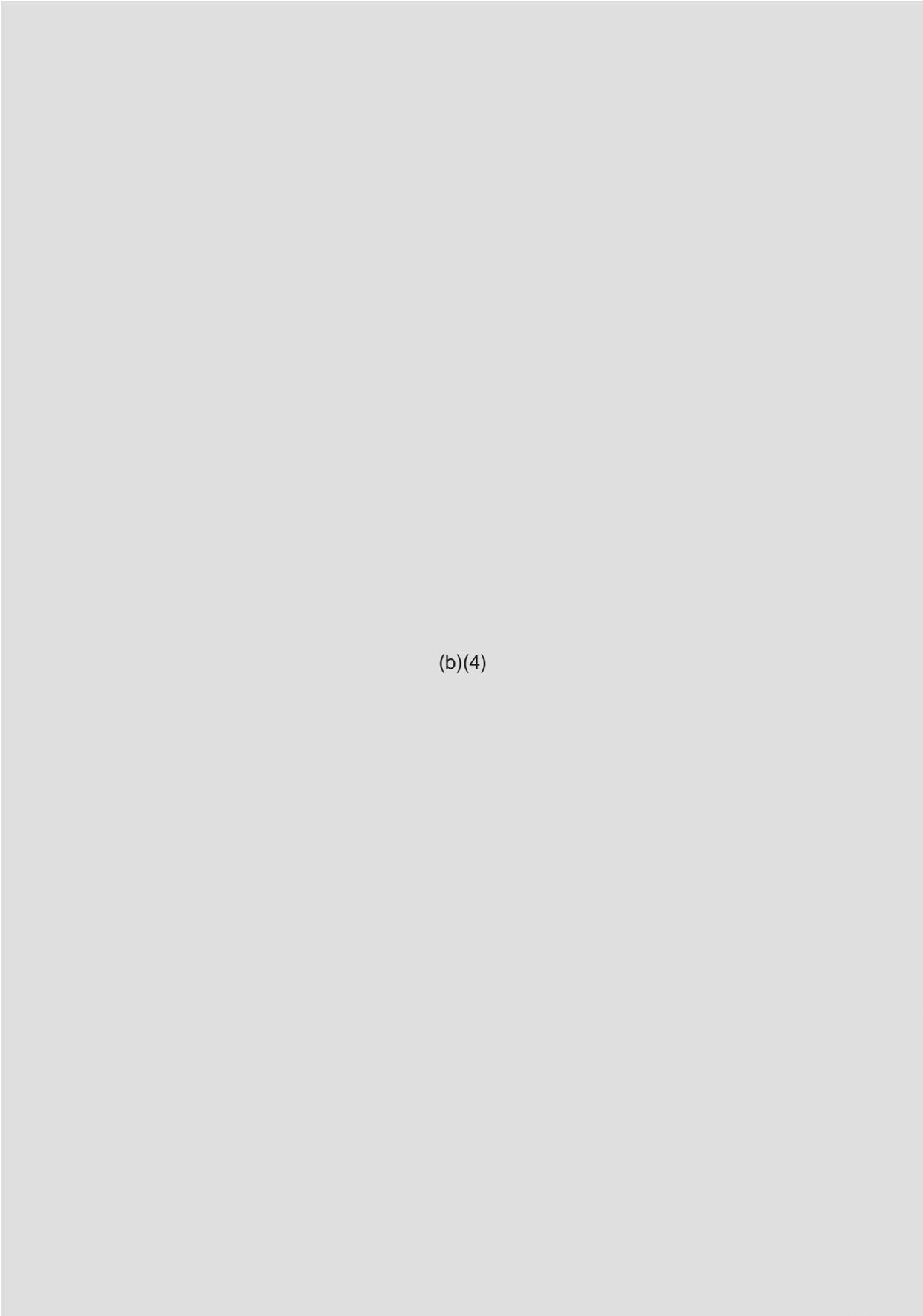

Naomi Gong
Regulatory Affairs Project Manager
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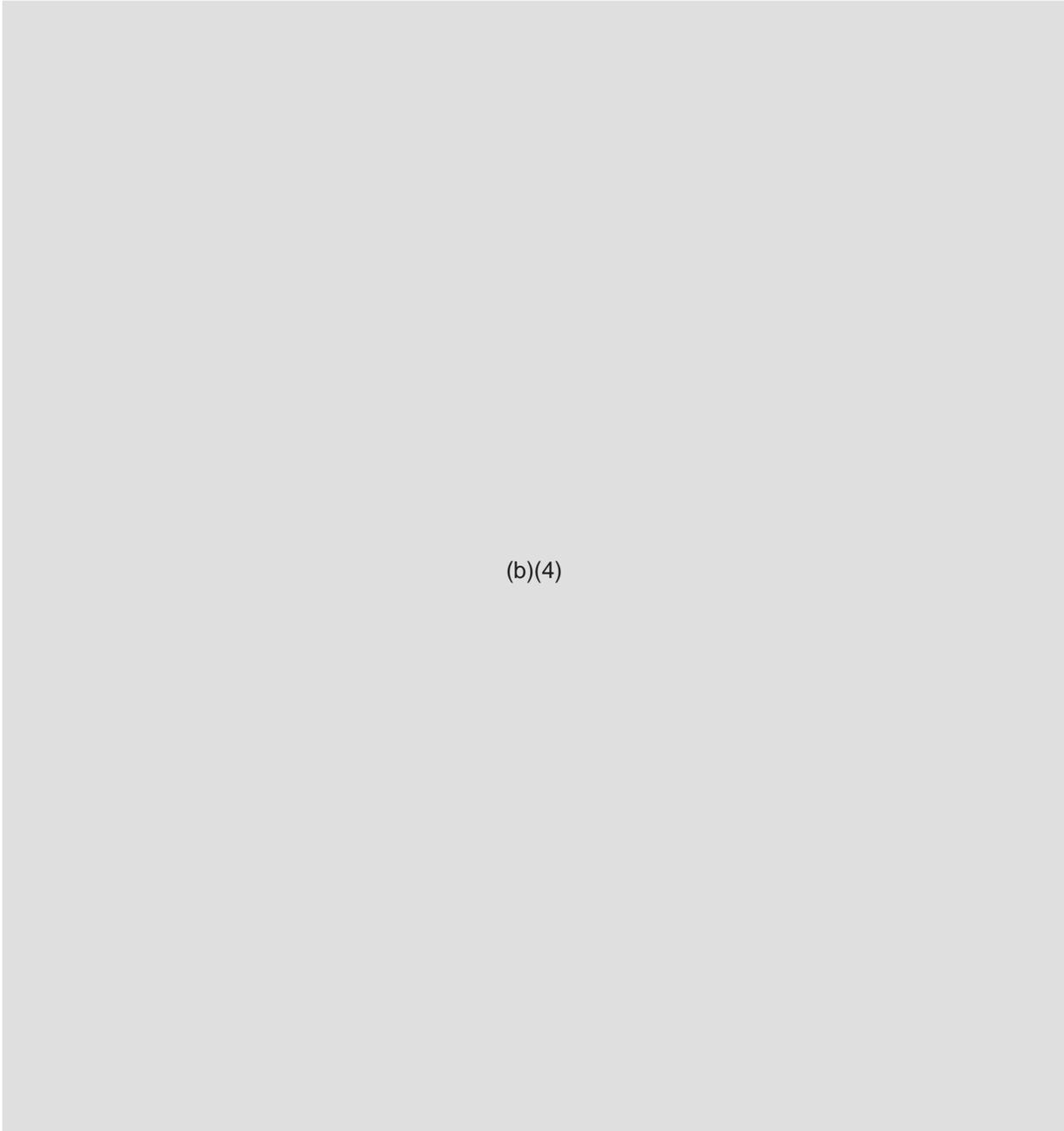
510(k) K093397 - Supplement



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In closing, we hope this supplemental information is useful for you in completing the review of this submission.

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510(k) K093397 - Supplement

Attachments

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

Attachment B:

Attachment C:

(b)(4)

Attachment D:

Attachment A

Performance Characteristics of Microcatheter Systems in a Standardized Tortuous Pathway

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

BACKGROUND 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

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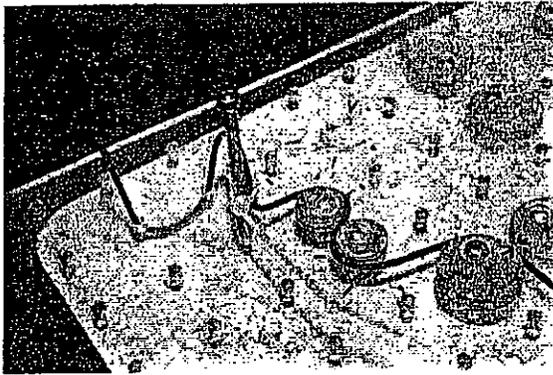


FIG 1. Three-dimensional model of pathway constructed of clear polytetrafluoroethylene tubing simulating the intracranial carotid circulation.

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 (Mediatech/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

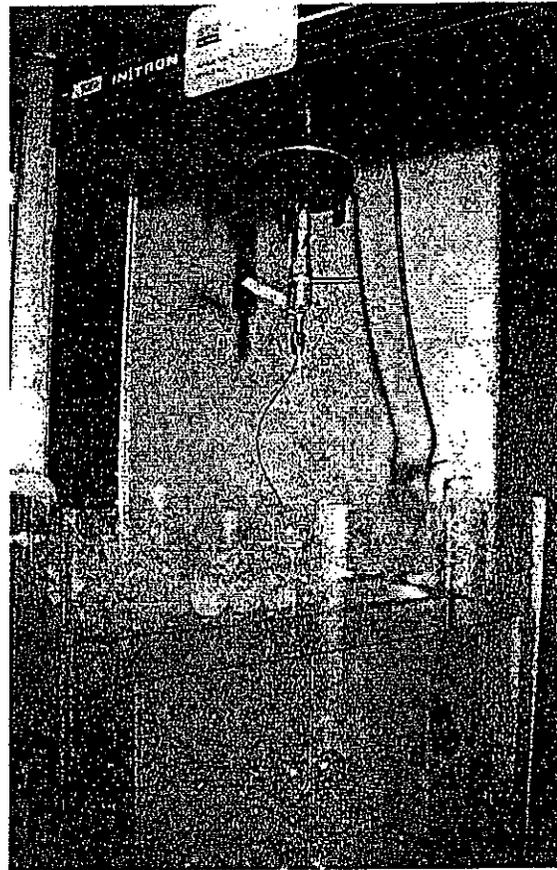


FIG 2. Proximal buckling of the FasTracker MX catheter because of excessive load forces.

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.

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

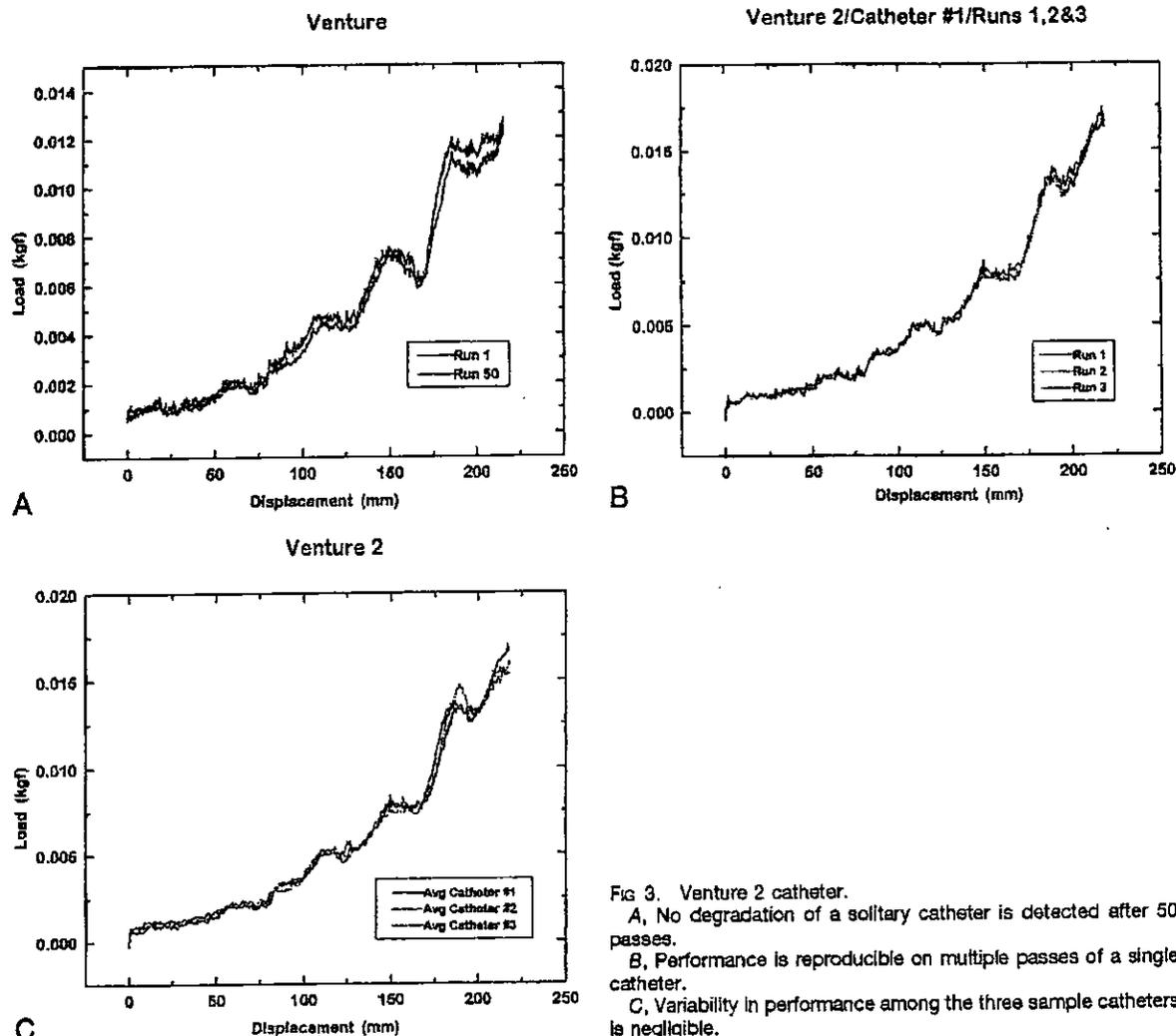


FIG 3. Venture 2 catheter.
 A, No degradation of a solitary catheter is detected after 50 passes.
 B, Performance is reproducible on multiple passes of a single catheter.
 C, Variability in performance among the three sample catheters is negligible.

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 irreversibly, 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

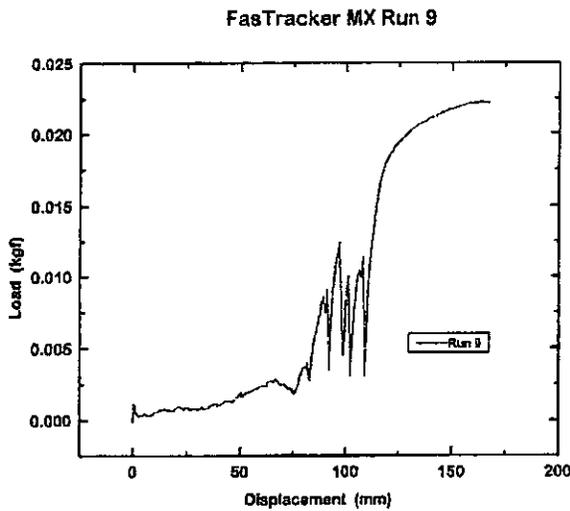


FIG 4. FasTracker MX catheter. Multiple load peaks corresponding to multiple successive episodes of buckling and paroxysmal advancement of the catheter are observed between 75 and 110 mm of displacement. Above 110 mm of displacement, the catheter buckled in an irrecoverable manner, with an excessive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

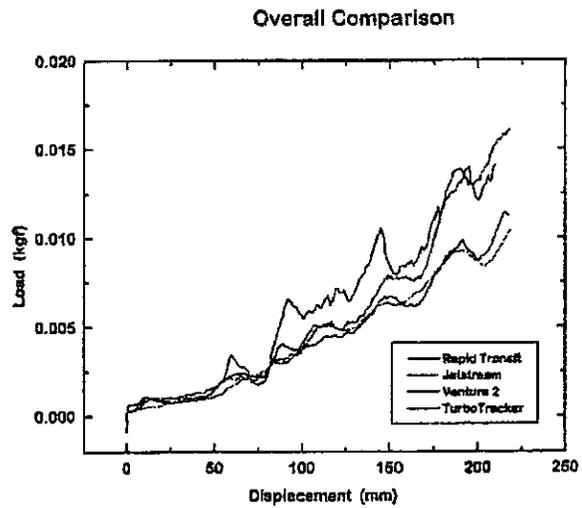


FIG 5. Overall comparison of the four reinforced catheters. Average load forces required by three catheters (three passes of each) are plotted against displacement. Lower maximum load forces are required by the Jetstream and Rapid Transit catheters but may not be clinically significant.

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).

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. Poly-

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

tetrafluoroethylene 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,

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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 non-braided 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 val-

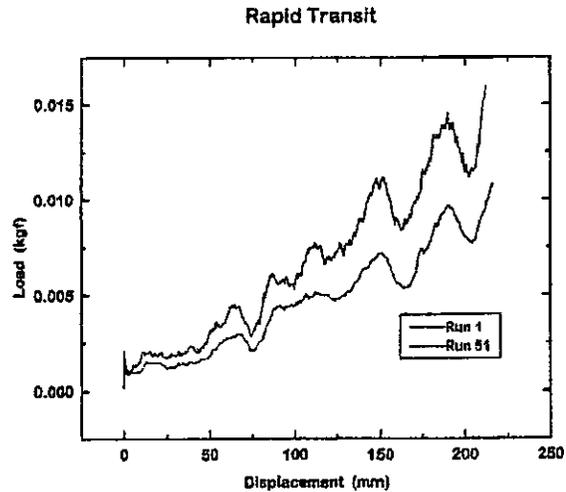


Fig 6. Load forces required by the Rapid Transit catheter actually diminish with multiple passes. This effect, which can be observed after only one or two passes, also occurred with the Jetstream catheter. Improvement may be the result of the softening of either the catheter or the hydrophilic coating.

ues 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.

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-

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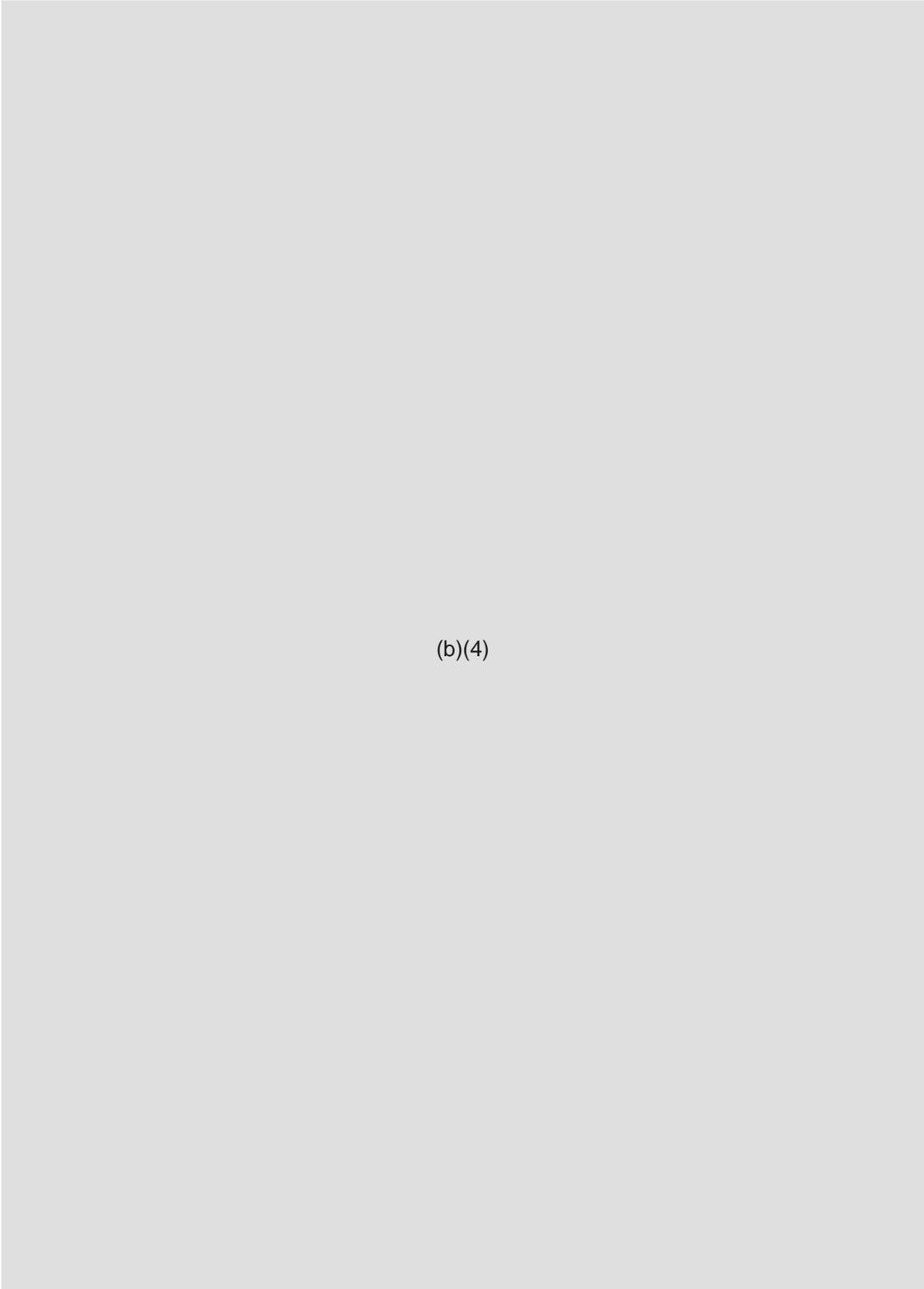
AJNR: 19, September 1998

hance the safety of superselective intracranial catheterization.

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Attachment B



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Confidential

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Attachment C

Pages 251 through 262 redacted for the following reasons:

(b)(4)-Trade Secret-Test Protocol/Pathology Report