

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

K112226

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 29 2011

Trade Name: HydroCoil Embolic System (HES)

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California 92780
U.S.A.

Contact: Laraine Pangelina

Predicate Device: HydroCoil Embolic System (K070656, K080666, K091641)

Device Description: The HES consists of implantable coil made of platinum alloy with inner hydrogel core. The helical-shaped implantable coil is available in various outer dimensions and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end of the pusher is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

The RD11-006 HES is a line extension which is substantially the same as the predicate devices (K070656, K080666, K091641). The implantable coil portion of both the predicate and the subject device is constructed from platinum alloy wire. The RD11-006 implantable coil is constructed of an oval-shaped platinum alloy wire, whereas the predicate devices are constructed of a round platinum alloy wire. All other materials and design features are the same for both the predicate and subject devices.

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

MicroVention, Inc.**Special 510(k)****HydroCoil Embolic System (HES) – RD11-006 Line Extension****Bench Test Summary:**

Test	Result
Visual Inspection	Met same criteria as predicate
Dimensional Measurement	Met same criteria as predicate
Simulated Use <ul style="list-style-type: none"> • Introduction • Tracking • Reposition / Deployment • Detachment • Overall Performance 	Met same criteria as predicate
Spring Constant	Met same criteria as predicate
Gel Expansion	Met same criteria as predicate
Weld Tensile	Met same criteria as predicate
Advancement / Retraction Force	Met same criteria as predicate

Predicate / Subject Device Comparison:

Feature	Predicate Device	Subject Device
Coil shape	Helical	Same
Implant diameter	2 mm – 10 mm	2 mm – 7 mm
Implant restrained length	1 cm – 30 cm	2 cm – 10 cm
Deliver pusher length	185 cm	Same
Main coil wire material	Platinum/Tungsten (92/8 %) alloy	Same
Coupler material	Platinum (90%) / iridium (10%)	Same
Adhesive material	Dymax 1128-AM-VT	Same
Implant to pusher material	Polyolefin Elastomer	Same
Stretch resistant filar material	Polyolefin Elastomer	Same
Gel material	Hydrophilic Copolymer	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser, pouch, carton	Same

Summary of Substantial Equivalence:

The HES coils that are the subject of this submission are substantially equivalent to the predicate device with regard to intended use, patient population, device design, materials, processes, and operating principal.



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

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

SEP 29 2011

Re: K112226

Trade/Device Name: HydroCoil Embolic System (HES)
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: August 02, 2011
Received: August 03, 2011

Dear Ms. Pangelina:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

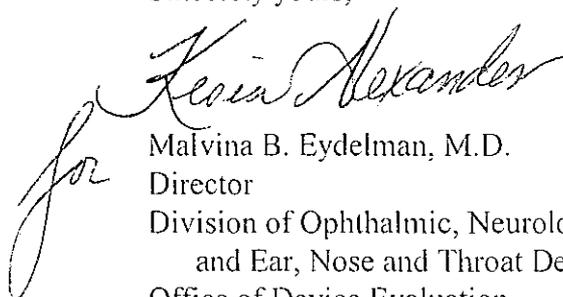
Page 2 - Ms. Loraine Pangelina

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/ucml15809.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,

A handwritten signature in cursive script, appearing to read "for Malvina B. Eydelman". The signature is written in black ink and is positioned to the left of the typed name and title.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

INDICATIONS FOR USE

510(k) Number (if known): K112226

Device Name: HydroCoil Embolic System (HES)

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

 ALEX BAILEY

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112226

NNDB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K 112226 / AI

To: Division Director: NE / DONEI

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy ^{an email response} of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

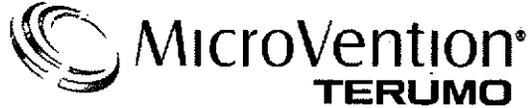
This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: *Alfonso*

Date: 10/20/11

Dec 10 2011

K112226/A1



September 1, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002
Attn: Alex M. Bailey, Ph.D.

FDA CDRH DMC
OCT 19 2011
Received

KSG

**Subject: 510(k) #K112226, HydroCoil Embolic System (HES) line extension
Response to Telephone Hold/Additional Information Request dated September 1, 2011**

Dear Dr. Bailey,

In response to the letter which you sent to me via email today, I have attached a revised copy of the Summary of Safety and Effectiveness for K112226 which includes the additional information as requested. The additional information requested in item (a) is located in the second paragraph of the Device Description section. The additional information requested in item (b) is located in the Bench Test Summary section.

The attached Summary of S&E is provided without "Confidential" at the bottom of the page, so it can be released via FOI. I believe this adequately addresses your request. If you have any question about the attachment, please contact me.

Best Regards,

Laraine Pangelina
Regulatory Affairs Project Manager
MicroVention, Inc.
Tel: (714) 247-8150
Fax: (714) 247-8014
laraine.pangelina@microvention.com

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: HydroCoil Embolic System (HES)

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
1311 Valencia Avenue
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Contact: Laraine Pangelina

Predicate Device: HydroCoil Embolic System (K070656, K080666, K091641)

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Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

Bench Test Summary:

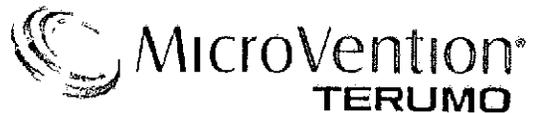
Test	Result
Visual Inspection	Met same criteria as predicate
Dimensional Measurement	Met same criteria as predicate
Simulated Use <ul style="list-style-type: none"> • Introduction • Tracking • Reposition / Deployment • Detachment • Overall Performance 	Met same criteria as predicate
Spring Constant	Met same criteria as predicate
Gel Expansion	Met same criteria as predicate
Weld Tensile	Met same criteria as predicate
Advancement / Retraction Force	Met same criteria as predicate

Predicate / Subject Device Comparison:

Feature	Predicate Device	Subject Device
Coil shape	Helical	Same
Implant diameter	2 mm – 10 mm	2 mm – 7 mm
Implant restrained length	1 cm – 30 cm	2 cm – 10 cm
Deliver pusher length	185 cm	Same
Main coil wire material	Platinum/Tungsten (92/8 %) alloy	Same
Coupler material	Platinum (90%) / Iridium (10%)	Same
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Implant to pusher material	Polyolefin Elastomer	Same
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MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser, pouch, carton	Same

Summary of Substantial Equivalence:

The HES coils that are the subject of this submission are substantially equivalent to the predicate device with regard to intended use, patient population, device design, materials, processes, and operating principal.



September 1, 2011

FDA CDRH DMC

OCT 19 2011

Received KSG

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002
Attn: Alex M. Bailey, Ph.D.

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Laraine Pangelina
Regulatory Affairs Project Manager
MicroVention, Inc.
Tel: (714) 247-8150
Fax: (714) 247-8014
laraine.pangelina@microvention.com

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

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

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

SEP 29 2011

Re: K112226

Trade/Device Name: HydroCoil Embolic System (HES)
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: August 02, 2011
Received: August 03, 2011

Dear Ms. Pangelina:

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

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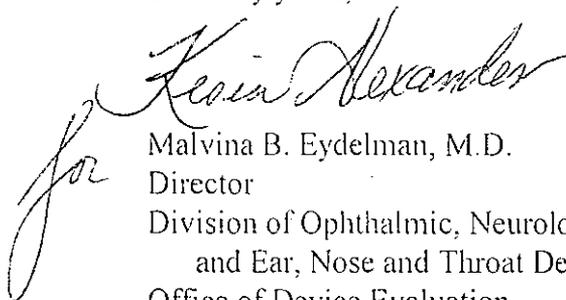
Page 2 - Ms. Loraine Pangelina

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/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

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Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

INDICATIONS FOR USE

510(k) Number (if known): K112226

Device Name: HydroCoil Embolic System (HES)

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ALEX BAILEY

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112226



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

September 08, 2011

MICROVENTION, INC.
1311 VALENCIA AVE
TUSTIN, CALIFORNIA 92780
ATTN: LARAIN PANGELINA

510k Number: K112226

Product: HYDROCOIL EMBOLIC SYSTEM (HES)

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate 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>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". 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 AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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 yours,

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



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

August 04, 2011

MICROVENTION, INC.
1311 VALENCIA AVE
TUSTIN, CALIFORNIA 92780
ATTN: LARAIN PANGELINA

510k Number: K112226

Received: 8/3/2011

Product: HYDROCOIL EMBOLIC SYSTEM (HES)

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

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

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

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

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

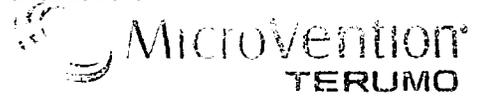
Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number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

Sincerely,

510(k) Staff

NE / DONEO

K112226



FDA CDRH DMC

August 2, 2011

AUG - 3 2011

U.S. Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center (WO66-G0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Received

K-9

RE: Special 510(k) for HydroCoil Embolic System (HES), Line Extension

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act as amended by the Medical Device Amendment of 1976, MicroVention, Inc. hereby submits this Special Premarket Notification 510(k) for the HydroCoil Embolic System (HES).

The subject of this Special 510(k) is the RD11-006 HES, a line extension to the current HydroSoft HES. The RD11-006 HES is substantially the same as the predicate devices (HydroSoft HES, K070656, K080666, K091641).

(b)(4) (b)(4)
(b)(4) (b)(4)

We believe this modification is eligible for the Special 510(k) since it has the same fundamental scientific technology, basic design, operating principle and intended use, and uses the same material as the predicate device.

We are submitting 2 paper copies of this submission as well as an exact duplicate electronic copy on a CD. The CD also includes copies of the Summary of Safety & Effectiveness and the Indications for Use Statement without "Confidential", as well as a copy of this cover letter.

Statement of Confidentiality: MicroVention, Inc. considers the information in this submission to be confidential. 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.

If there are any questions, please contact me by phone at 714-247-8150, by fax at 714-247-8014, or by email at laraine.pangelina@microvention.com.

Sincerely,

Laraine Pangelina
Regulatory Affairs Project Manager



August 2, 2011

U.S. Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center (WO66-G0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Special 510(k) for HydroCoil Embolic System (HES), Line Extension

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(b) (4)

(b)(4)

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If there are any questions, please contact me by phone at 714-247-8150, by fax at 714-247-8014, or by email at laraine.pangelina@microvention.com.

Sincerely,

Laraine Pangelina
Regulatory Affairs Project Manager



SPECIAL 510(k): DEVICE MODIFICATION
HYDROCOIL EMBOLIC SYSTEM (HES)
LINE EXTENSION

AUGUST 2, 2011

MICROVENTION, INC.

1311 Valencia Avenue
Tustin, CA 92780
Phone: 714-247-8000
Fax: 714-247-8014

This document contains confidential and proprietary information.
Unauthorized use and reproduction is strictly prohibited

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

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MicroVention, Inc.

Special 510(k)

HydroCoil Embolic System (HES) – RD11-006 Line Extension

SECTION 1 SPECIAL 510(K) ADMINISTRATIVE REQUIREMENTS

- **Medical Device User Fee Cover Sheet**
- **CDRH Premarket Review Submission Cover Sheet**
- **Truthful and Accurate Statement**
- **510(k) Summary**
- **Indications for Use Statement**
- **Form FDA 3654**
- **Form FDA 3674**
- **Declaration of Conformity**
- **Design Control Activities Summary**

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

Medical Device User Fee Cover Sheet

Site: null

Page 1 of 1

Form Approved: OMB No. 0910-011. 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) (6) Write the Payment Identification number of _____
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/cover-sheet.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 Kevin Daly 2.1 E-MAIL ADDRESS kevin.daly@microvention.com 2.2 TELEPHONE NUMBER (Include Area code) 714-247-8043 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"/> The sole purpose of the application is to support conditions of use for a pediatric population <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 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		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes 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 the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (6)		23-Mar-2011

FORM FDA 2001 (01-007)

"Close Window" Print Cover sheet

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

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>):		

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

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>): Lline extension of a legally marketed device.		

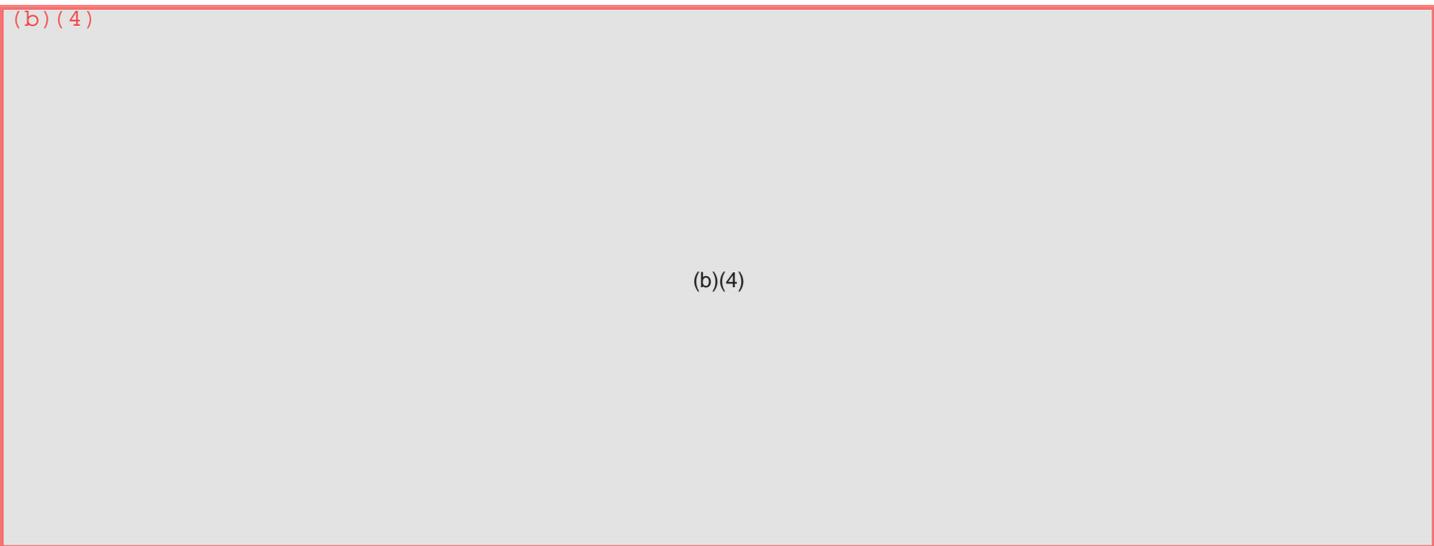
SECTION E						ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS											
Product codes of devices to which substantial equivalence is claimed												Summary of, or statement concerning, safety and effectiveness information					
1	HCG	2		3		4		<input checked="" type="checkbox"/> 510 (k) summary attached									
5		6		7		8		<input type="checkbox"/> 510 (k) statement									
Information on devices to which substantial equivalence is claimed (if known)																	
<i>510(k) Number</i>						<i>Trade or Proprietary or Model Name</i>						<i>Manufacturer</i>					
1	K070656					1	HydroCoil Embolic System					1	MicroVention, Inc.				
2	K080666					2	HydroCoil Embolic System					2	MicroVention, Inc.				
3	K091641					3	HydroCoil Embolic System					3	MicroVention, Inc.				

SECTION F												PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS						
Common or usual name or classification Neurovascular Embolization Device																		
Trade or Proprietary or Model Name for This Device																		
1	HydroCoil Embolic System (HES)										1	100202RD11006-V, 100204RD11006-V, 100206RD11006-V, 100304RD11006-V, 100306RD11006-V, 100406RD11006-V, 100408RD11006-V, 100410RD11006-V, 100508RD11006-V, 100510RD11006-V, 100608RD11006-V, 100610RD11006-V, 100710RD11006-V						
2											2							
FDA document numbers of all prior related submissions (regardless of outcome)																		
1	2	3	4	5	6													
Data Included in Submission																		
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials																		

SECTION G												PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS											
Product Code HCG/KRD				C.F.R. Section (if applicable) 882.5950/870.3300				Device Class															
Classification Panel Neurological Devices												<input checked="" type="checkbox"/> Class II						<input type="checkbox"/> Class III <input type="checkbox"/> Unclassified					
Indications (from labeling)																							
The HES is Intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.																							

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

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	FDA Establishment Registration 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.		Establishment Registration Number 2032493	
Division Name (if applicable) N/A		Phone Number (including area code) (714) 247-8000	
Street Address 1311 Valencia Ave.		FAX Number (including area code) (714) 247-8014	
City Tustin		State / Province CA	ZIP/Postal Code 92780 Country USA
Contact Name Laraine Pangelina	Contact Title Regulatory Affairs Project Manager	Contact E-mail Address laraine.pangelina@microvention.com	



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration 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	

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

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					

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

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

As required by 21 CFR §807.87(k)

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

Signature

Laraine Pangelina, Regulatory Affairs Project Manager
Printed Name

Date

Premarket Notification Number (if known)

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: HydroCoil Embolic System (HES)

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
 1311 Valencia Avenue
 Tustin, California 92780
 U.S.A.

Contact: Laraine Pangelina

Predicate Device: HydroCoil Embolic System (K070656, K080666, K091641)

Device Description: The HES consists of implantable coil made of platinum alloy with inner hydrogel core. The helical-shaped implantable coil is available in various outer dimensions and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end of the pusher is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

Bench Test Summary:

Test	Result
Visual Inspection	Met same criteria as predicate
Dimensional Measurement	Met same criteria as predicate
Simulated Use	Met same criteria as predicate
Spring Constant	Met same criteria as predicate
Gel Expansion	Met same criteria as predicate
Weld Tensile	Met same criteria as predicate
Advancement / Retraction Force	Met same criteria as predicate

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

**Predicate / Subject
 Device Comparison:**

Feature	Predicate Device	Subject Device
Coil shape	Helical	Same
Implant diameter	2 mm – 10 mm	2 mm – 7 mm
Implant restrained length	1 cm – 30 cm	2 cm – 10 cm
Deliver pusher length	185 cm	Same
Main coil wire material	Platinum/Tungsten (92/8 %) alloy	Same
Coupler material	Platinum (90%) / iridium (10%)	Same
Adhesive material	Dymax 1128-AM-VT	Same
Implant to pusher material	Polyolefin Elastomer	Same
Stretch resistant filar material	Polyolefin Elastomer	Same
Gel material	Hydrophilic Copolymer	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser, pouch, carton	Same

**Summary of Substantial
 Equivalence:**

The HES coils that are the subject of this submission are substantially equivalent to the predicate device with regard to intended use, patient population, device design, materials, processes, and operating principal.

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: HydroCoil Embolic System (HES)

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(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)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ AAMI/ANSI/ISO 10993-1		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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 ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: <u>Vascular and Neurovascular Embolization Devices Dated February 25, 2004.</u>		
<small> 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 </small>		

MicroVention, Inc.
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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		
<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>		
<p align="center">Paperwork Reduction Act Statement</p> <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 align="center">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p 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>		

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See OMB Statement on Reverse, Form Approved: CMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))		
(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)		
SPONSOR / APPLICANT / SUBMITTER INFORMATION		
1. NAME OF SPONSOR/APPLICANT/SUBMITTER Laraine Pangelina	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES	
3. ADDRESS (Number, Street, State, and ZIP Code) MicroVention, Inc. 1311 Valencia Avenue Tustin, CA 92780	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 714-247-8150 (Fax) 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)		
MicroPlex Coils System (MCS), Cosmos 18 <hr/> <hr/> <hr/>		
APPLICATION / SUBMISSION INFORMATION		
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other		
7. INCLUDE IND/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)		
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES		
CERTIFICATION STATEMENT / INFORMATION		
9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)		
<input checked="" type="checkbox"/> 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.		
<input type="checkbox"/> 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.		
<input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.		
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)" UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)		
NCT Number(s): _____		
The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.		
11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Laraine Pangelina (Title) Regulatory Affairs Project Manager	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) MicroVention, Inc. 1311 Valencia Avenue Tustin, CA 92780	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 714-247-8150 (Fax) 714-247-8914	15. DATE OF CERTIFICATION

Form FDA 3674 (11/08) (FRONT)

FSC (English) (301) 441-3090 01

MicroVention, Inc.

Special 510(k)

HydroCoil Embolic System (HES) – RD11-006 Line Extension

Declaration of Conformity with Design Controls

HES Line Extension

I certify, to the best of my knowledge that:

- As required by the risk analysis, all design verification and design validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and
- The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Laraine Pangelina
Regulatory Affairs Project Manager
MicroVention, Inc

Date

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

Design Control Activities Summary, HES Line Extension

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
(b) (4)				

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

SECTION 2 EXECUTIVE SUMMARY

The Microvention HydroCoil Embolic System (HES) is for the treatment of endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations (AVM), and arteriovenous fistulae (AVF). The coils are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

The HES consists of an implantable coil made of platinum alloy with an inner hydrogel core. The coil is attached to a V-Trak delivery pusher via a polymer filament. The proximal end of the pusher is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

The subject of this Special 510(k) is the RD11-006 HES, a line extension to the current HydroSoft HES. The RD11-006 HES is substantially the same as the predicate devices (HydroSoft HES, K070656, K080666, K091641). The RD11-006 is designed to have

(b) (4)

(b)(4)

A detailed comparison of the subject device and the predicate devices is presented in the following sections of this submission.

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

SECTION 3 GENERAL INFORMATION

3.1 PREDICATE DEVICE INFORMATION

HydroCoil Embolic System (HES), HydroSoft (K070656, K080666, K091641)

3.2 DEVICE CLASSIFICATION INFORMATION

Device Trade Name: HydroCoil Embolic System (HES)
Device Generic Name: Neurovascular Embolization Device
Classification Name: Neurovascular Embolization Device
CFR Classification: 21 CFR 882.5950
Device Class: Class II
FDA Panel: Neurological Devices
Product Code: HCG

3.3 MANUFACTURER'S NAME, ADDRESS AND REGISTRATION

MicroVention, Inc. 1311 Valencia Avenue Tustin, CA 92780	<u>Contact</u> Laraine Pangelina Regulatory Affairs Project Manager Phone: 714-247-8150 Fax: 714-247-8014
Facility Registration: #2032493	

3.4 STERILIZATION FACILITY'S NAME, ADDRESS AND REGISTRATION

Beam One (e-beam)
9020 Activity Road, Suite D
San Diego, CA 92126

3.5 INTENDED USE

The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

3.6 LABELING INFORMATION

The draft Instructions for Use (IFU) are the same as the predicate device and are provided in [Attachment 1](#). A representative package label is also provided in [Attachment 1](#).

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

SECTION 4 DEVICE DESCRIPTION AND COMPARISON WITH CLEARED DEVICE

4.1 DEVICE DESCRIPTION

The subject of this Special 510(k) is the RD11-006 HES, a line extension to the current HydroSoft HES. The RD11-006 HES is substantially the same as the predicate devices (HydroSoft HES, K070656, K080666, K091641). The RD11-006 is designed to have improved filling attributes with repositioning time comparable to other commercialized HES coils when used with either a microcatheter 10 system or a microcatheter 18 system. This is

(b) (4)

(b)(4)

All other materials and design features are the same as the predicate device.

(b) (4)

(b)(4)

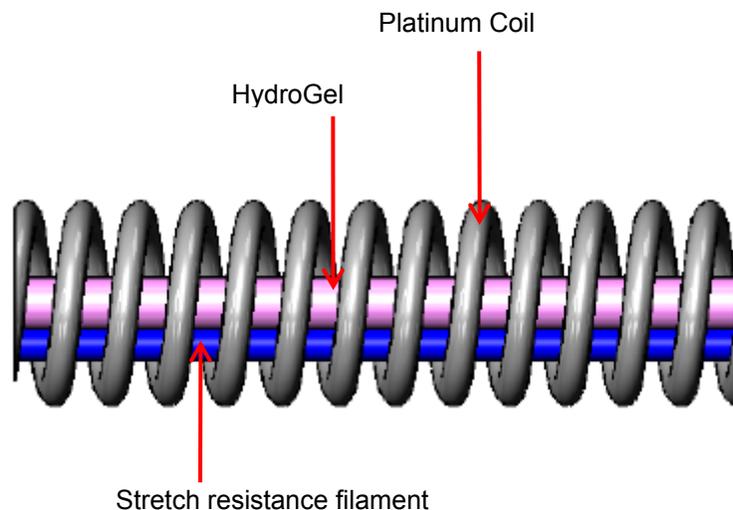


Figure 1
HydroSoft HES Implantable Coil (predicate and subject devices)

The coil is attached to a V-Trak delivery pusher via a polymer filament. The delivery pusher contains radiopaque positioning markers at the distal end. The proximal end is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

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HydroCoil Embolic System (HES) – RD11-006 Line Extension

Table 2 below lists the models of the cleared HydroSoft HES and the RD11-006 HES Line Extension.

Table 2 – HydroSoft Models - Predicate and Subject Device

Predicate HydroSoft HES (K070656, K080666, K091641)						RD11-006 HES		
Model No.	Coil OD mm	Coil Length cm	Model No.	Coil OD mm	Coil Length cm	Model No.	Coil OD mm	Coil Length cm
100101H2HS-V	1	1	100406H2HS-V	4	6	100202RD11006-V	2	2
100102H2HS-V	1	2	100408H2HS-V	4	8	100204RD11006-V	2	4
100103H2HS-V	1	3	100410H2HS-V	4	10	100206RD11006-V	2	6
100104H2HS-V	1	4	100506H2HS-V	5	6	100304RD11006-V	3	4
100105H2HS-V	1	5	100508H2HS-V	5	8	100306RD11006-V	3	6
100151H2HS-V	1.5	1	100510H2HS-V	5	10	100406RD11006-V	4	6
100152H2HS-V	1.5	2	100515H2HS-V	5	15	100408RD11006-V	4	8
100153H2HS-V	1.5	3	100520H2HS-V	5	20	100410RD11006-V	4	10
100154H2HS-V	1.5	4	100606H2HS-V	6	6	100508RD11006-V	5	8
100155H2HS-V	1.5	5	100608H2HS-V	6	8	100510RD11006-V	5	10
100201H2HS-V	2	1	100610H2HS-V	6	10	100608RD11006-V	6	8
100202H2HS-V	2	2	100615H2HS-V	6	15	100610RD11006-V	6	10
100203H2HS-V	2	3	100620H2HS-V	6	20	100710RD11006-V	7	10
100204H2HS-V	2	4	100715H2HS-V	7	15			
100206H2HS-V	2	6	100720H2HS-V	7	20			
100208H2HS-V	2	8	100730H2HS-V	7	30			
100254H2HS-V	2.5	4	100815H2HS-V	8	15			
100256H2HS-V	2.5	6	100820H2HS-V	8	20			
100304H2HS-V	3	4	100830H2HS-V	8	30			
100306H2HS-V	3	6	100920H2HS-V	9	20			
100308H2HS-V	3	8	100930H2HS-V	9	30			
100310H2HS-V	3	10	101020H2HS-V	10	20			
100404H2HS-V	4	4	101030H2HS-V	10	30			

An engineering drawing of the RD11-006 HES is provided in [Attachment 2](#).

MicroVention, Inc.

Special 510(k)

HydroCoil Embolic System (HES) – RD11-006 Line Extension

4.3 SUBSTANTIAL EQUIVALENCE SUMMARY

In summary, the RD11-006 HES has the same design parameters and the same intended use as the legally marketed predicate device. Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. Therefore, it is our conclusion that they are substantially equivalent to the predicate device.

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SECTION 5 SUMMARY OF DESIGN CONTROL ACTIVITIES

5.1 RISK ANALYSIS

The HES is 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 mitigation measures such as physician training program, labeling warnings and instructions for use.

The following Risk Management documentation is provided in [Attachment 3](#) of this submission:

- QP 4.1, Quality Procedure Design and Development Process
- QP 4.8, Quality Assurance Risk Management Procedure
- RA020001 - Risk Management File

5.2 LIST OF VOLUNTARY STANDARDS

The HES is designed, developed and tested using the applicable requirements of the standards listed in **Table 3**:

Table 3 Standards

Standard No.	Standard Name	Edition
FDA Guidance	Vascular and Neurovascular Embolization Devices	2004
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/ISO11137-1	Medical Devices- Sterilization of Health Care Products – Radiation Part 1 – Requirements for Development, Validation, and Sterilization Process for Medical Devices.	2006
ISO 13485	Particular requirement for application of ISO 9001	2003
ISO 10993-1	Biological evaluation of medical devices	1994
EN 980	Graphical Symbol used in Labeling of Medical Devices	2008
ISO 11607 -1, -2	Packaging for Terminally Sterilized Medical Devices	2006
EN 1041	“Terminology, Symbols and Information Supplied with Devices.”	1998

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5.3 DESIGN VERIFICATION AND VALIDATION TEST SUMMARY

5.3.1 In Vitro Bench Testing

Verification and validation testing was performed on the RD11-006 HES according to written protocol TP11-131. A summary of the results from test report TR11-131 follows. The test protocol and test report are provided in [Attachment 4](#).

Table 4 below summarizes the RD11-006 HES test plan:

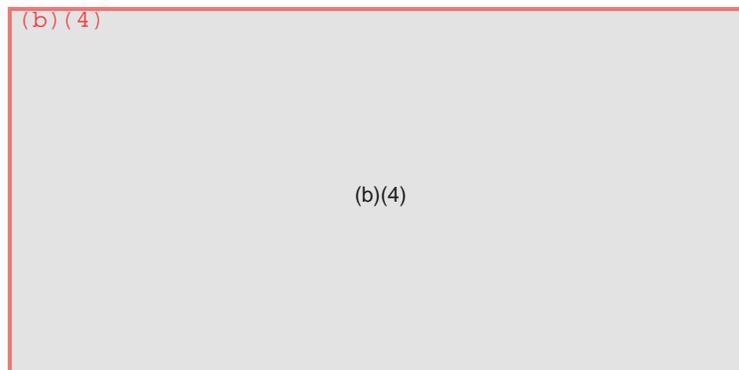
Table 4 RD11-006 HES Test Plan Summary

Test	%Confidence / %Reliability	Sample Size	Acceptance Criteria
Visual Inspection	90/90	54	Per product drawing
Implant Diameter	90/90	54	±0.5mm
Simulated Use ¹	90/90	24	All ratings ≥ 3
Detachment	90/90	24	Detached within 3 attempts
Gel Expansion	90/90	24	≥0.017□
Coil/Coupler Weld Tensile Test	90/80	15	0.080 lbf minimum
Spring Constant	90/80	15	0.09 oz/in. minimum
Advance/Retract Force	90/80	15 (Headway 17 or equivalent)	0.145 lbf maximum
		15 (Headway 21 or equivalent)	

¹Simulated Use testing included:

- Introduction
- Tracking
- Reposition / Deployment
- Detachment
- Overall Performance.

To simulate the clinical environment, the simulated use test is performed using the “**In-Vitro “Simulated Use” Test in Simulated Intra-Cranial Silicone Aneurysms**” bench test model. The test simulates a neurointerventional embolization procedure in an aneurysm. This model simulates the three-dimensional pathway of the intracranial carotid circulation. Below is a diagram of the simulated use model.



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Visual Inspection

The visual inspection was completed using the product drawing. Results are shown in the table below:

Implant Size (mm x cm)	Sample Size	Results
2 x 2	10	Pass
3 x 4	8	Pass
4 x 6	10	Pass
5 x 8	8	Pass
6 x 10	8	Pass
7 x 10	10	Pass

Simulated Use

Simulated use testing was conducted to verify that the **RD11-006** HES coils meet the established performance specifications in a clinically simulated environment. Testing was performed using both 0.021” and 0.015” microcatheters. Results are shown in the table below.

Simulated Use	Introduction	Tracking	Reposition/Deployment	Detachment	Overall Performance
Sample Size	24	24	24	24	24
Acceptance Criteria	≥ 3	≥ 3	≥ 3	≥ 3	≥ 3
Minimum Score	5	4	5	5	5
Results	Pass	Pass	Pass	Pass	Pass

Spring Constant

The spring constant force of the coil was measured after simulated use testing. Results are shown in the table below:

Sample Size: 15	Results in oz/in	Results in N/mm
Average	(b) (4)	
Standard Deviation		
Min		
Max		
Acceptance Criteria		
Conclusion	Pass	Pass

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Coil to Coupler Weld Tensile Strength

The coil/coupler weld tensile strength was assessed. Results are summarized in the table below:

Sample Size: 15	Results in lbf	Results in N
Average	(b)(4)	
Standard Deviation		
Min		
Max		
Acceptance Criteria		
Conclusion	Pass	Pass

Gel Expansion

This test provides a method to determine the diameter of hydrogel material during expansion. Each coil is measured at 3 random locations and the values from the 3 locations are averaged for the final result. The results are summarized in the table below:

Sample Size: 24	Gel Expansion OD @ 50 Minutes (in)
Average	(b)(4)
Standard Deviation	
Min	
Max	
Tolerance Limit	
Acceptance Criteria	
Results (Pass/Fail)	
¹ Source: Minitab/Johnson Transforma	
² Source: QP20.1E – Acceptance Sampling	

Advancement / Retraction Force

Advancement and Retraction Force testing was conducted using both Headway 17 microcatheters and Headway 21 microcatheters. The results are summarized in the tables below:

Advancement / Retraction Force using Headway 17 Sample Size: 15		
Statistical Analysis	Advancement Force (lbf)	Retraction Force(lbf)
Average (\bar{x})	(b)(4)	
Standard Deviation		
Min		
Max		
Acceptance Criteria		
Results (Pass/Fail)	Pass	Pass

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Advancement / Retraction Force using Headway 21 Sample Size: 15		
Statistical Analysis	Advancement Force (lbf)	Retraction Force(lbf)
Average	(b) (4)	
Standard Deviation	(b)(4)	
Min	(b)(4)	
Max	(b)(4)	
Acceptance Criteria	(b)(4)	
Results (Pass/Fail)	Pass	Pass

5.3.2 Biocompatibility

Biocompatibility studies were not repeated as the subject devices are made from the same material and using the same processes as those utilized in the fabrication of the predicate devices. The biological safety of the predicate coils has previously been verified in accordance with the ISO10993-1, Biological Evaluation of Medical Devices. The testing was performed by independent laboratories. The tables below summarize the tests conducted to provide assurance that the implant (permanent, blood contact) and the V-Trak delivery pusher (≤ 24 hrs, blood contact) have a safe biocompatibility profile.

HES Coils Implant Segment - Biocompatibility Summary

Test	Requirements	Results
Cytotoxicity		
MEM Elution	ISO 10993-5	Passed
ISO Cell Culture Agar Overlay	ISO 10993-5	Passed
Sensitization		
Sensitization-Guinea Pig Maximization	ISO 10993-10	Passed
Irritation		
ISO Intracutaneous Reactivity Evaluation	ISO 10993-10	Passed
Hemocompatibility		
Hemolysis	ISO 10993-4	Passed
Prothrombin Time Assay - ISO	ISO 10993-4	Passed
Systemic Toxicity		
Systemic toxicity (IV injection)	ISO 10993-11	Passed
Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Passed
Genetic Toxicology		
Bacteria Reverse Mutation Assay (Ames)	ISO 10993-3	Passed
Intramuscular Implantation		
7-day Muscle Implantation	ISO 10993-6	Passed
13-week Intramuscular Implantation Test	ISO 10993-6	Passed
26-week Intramuscular Implantation Test	ISO 10993-6	Passed

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Delivery Pusher Segment Biocompatibility Summary

Test	Requirements	Results
Cytotoxicity		
MEM Elution	ISO 10993-5	Passed
ISO Cell Culture Agar Overlay	ISO 10993-5	Passed
Sensitization		
Sensitization-Guinea Pig Maximization	ISO 10993-10	Passed
Irritation		
ISO Intracutaneous Reactivity Evaluation	ISO 10993-10	Passed
Hemocompatibility		
Hemolysis	ISO 10993-4	Passed
Prothrombin Time Assay - ISO	ISO 10993-4	Passed
Systemic Toxicity		
Systemic toxicity (IV injection)	ISO 10993-11	Passed
Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Passed

5.3.3 Packaging, Sterilization and Shelf Life

The packaging configuration and sterilization method for the RD11-006 HES is the same as the predicate devices. Additionally, no changes in materials or other key design attributes have been made to subject coils. Therefore, it was not necessary to perform additional or repeat packaging qualification, sterilization revalidation or shelf life testing.

Studies have been conducted on the predicate devices for accelerated aged testing equivalent to 5 years. Based on the result, we concluded that the RD11-006 HES will be labeled for 5-year shelf life. Accelerated aging studies are based on van't Hoff's rule, which states that a rise in temperature of 10° C will double the rate of a chemical reaction. The formula used for calculating aging study time periods is:

$$\text{Shelf Life} = t \times q^y$$

t = Accelerated Exposure Time (Days)
 q = Acceleration Factor (Coefficient of Aging)
 y = $\frac{\text{Elevated Storage Temp (°C)} - \text{Ambient Storage Temp (22 °C)}}{10}$

10

Packaging Components	1. Introducer Sheath: HDPE 2. Dispenser Coil: Polyethylene 3. Pouch: Polyester/Tyvek 4. Carton Box: Bleached Sulfate
Method of Supplying	Sterile and single use.
Sterility Validation Method	ANSI/AAMI/ISO 11137-1; 2006, Medical Devices- Sterilization of Health Care Products Radiation Part 1 – Requirements For Development, Validation and Sterilization Process for Medical Devices
Sterilization Method	Electron beam or gamma radiation 25-40 kGy
Sterility Assurance Level	(SAL) – 10 ⁻⁶
Contract Sterilization	Beam One (e-beam) 9020 Activity Road, Suite D, San Diego, CA 92126

MicroVention, Inc.

Special 510(k)

HydroCoil Embolic System (HES) – RD11-006 Line Extension

SECTION 6 QUALITY SYSTEM COMPLIANCE ACTIVITIES

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.

A copy of the MicroVention ISO 13485 Certificate is provided in the [Attachment 5](#).

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

SECTION 7 LIST OF ATTACHMENTS

Attachment 1	Product Labels, Instructions For Use
Attachment 2	Product Drawing
Attachment 3	Risk Analysis QP 4.1, Design and Development Quality Procedure QP 4.8, Risk Management Quality Procedure RA020001, Risk Management File
Attachment 4	Design Verification Protocol/Report (TP/TR11-131)
Attachment 5	MicroVention ISO Certificate

ATTACHMENT 1

LABELING

HydroSoft® 18

HydroCoil® Embolic System

Endovascular Embolization Coil

Spirale d'embolisation endovasculaire
 Endovaskuläre Embolisierungsspirale
 Espiral de embolización endovascular
 Spirale per embolizzazione endovascolare
 Espiral de embolização endovascular
 Endovaskulær emboliseringsspiral
 Endovaskulaire embolisatiecoil
 Endovaskulaarinen embolisaatiokierukka
 Endovaskulær emboliseringsspiral

Endovaskulær emboliseringsspiral
 Μικροσπειράμα ενδαγγειακού εμβολισμού
 Endovasküler Embolisasyon Sarmalı
 血管内栓塞线圈 혈관내 색전술 코일
 Спирала за вътресъдова емболизация
 Zavojnica za endovaskularnu embolizaciju
 Spirála pro endovaskulární embolizaci
 Endovaskulaarse emboliseerimise spiraalortu
 Endovascularis embolizációs tekercs

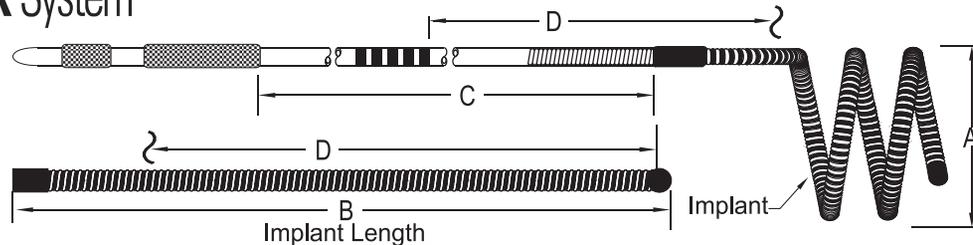
Endovaskulāras embolizācijas spirāle
 Endovaskulinės embolizacijos spirālė
 Spirala do embolizacji wewnątrznaczyniowej
 Bobină pentru embolizare endovasculară
 Спираль эндovasкулярной эмболизации
 Kalem za endovaskularnu embolizaciju
 Spiralna žica za endovaskularno embolizaciju

Helical

Stretch-Resistant

A	7 mm	B	10 cm	REF	Catalog Number
				"CATALOG No."	
C	175 cm	D	148 cm	LOT	Lot Number
				12345678	

V-Trak® System



HydroCoil 18 7 mm / 10 cm HydroSoft-Helical			
"Bar Code 1" REF: "Ref. No." LOT NO: 12345678	"Bar Code 2" REF: "Ref. No." LOT NO: 12345678	"Bar Code 1" REF: "Ref. No." LOT NO: 12345678	"Bar Code 2" REF: "Ref. No." LOT NO: 12345678

Non-pyrogenic Non pyrogène Pyrogenfrei Apirógeno Apirógeno Não-pirogênico	Non-pyrogen Pyrogeenvrij Pyrogeenitön Icke-pyrogen Ikke-pyrogen	Pirojenik Değildir 无致热原 비발열성 Апирогенна Nepirogen	Mittepörogeenne Nem pirogén Apirogēns Nepirogeniška Apirógenny Apirógen	Непирогенный Nepirogen Apirógeno
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MicroVention, Inc.
 1311 Valencia Avenue
 Tustin, CA 92780 USA
 PH: 714.247.8000
 www.microvention.com

CE 0297
 Made in U.S.A.

CONT 1
 Contents

STERILE R
 Sterilized Using Irradiation.

Attention:
 Refer to Instructions For Use.

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

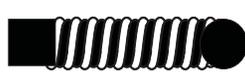
Do Not Reuse.

Date of Manufacture: 2011-07
 Use By: 2016-07

AW10004 Rev. A 2011-01 (LB10006) LBDRAFT-0710

HydroSoft® 18

HydroCoil® Embolic System



Helical

7 mm / 10 cm

"One Long Bar Code with BC1 and BC2 information"



Use By
 2016-07
 REF
 "Ref No."



Cases of chemical aseptic meningitis, edema, hydrocephalus and/or headaches have been associated with the use of embolization coils in the treatment of large and giant aneurysms. The physician should be aware of these complications and instruct patients when indicated. Appropriate patient management should be considered.

DRAFT
HydroCoil® Embolic System (HES)
(Endovascular Embolization Coil)
Instructions for Use

DEVICE DESCRIPTION

The MicroVention HydroCoil Embolic System (HES) consists of an implantable coil attached to a delivery system called a V-Trak® delivery pusher. The HES coils are platinum coils augmented with a hydrophilic polymer. The V-Trak® delivery pusher is powered by a V-Grip® detachment controller, which is provided separately.

The HES is available in several coil types based on the coil primary diameter and configuration. Each coil type must be delivered only through a wire-reinforced microcatheter with the minimum inner diameter specified. Within each coil type is a broad range of coil secondary (loop) diameters and lengths.

It is not necessary to pre-soften the HydroFrame™ or HydroSoft® implants.

Coil Type	Stretch Resistant	Minimum Microcatheter I.D.		Reposition Time	Gel Expansion Properties	
		inches	mm		To Coil OD	Beyond Coil OD
HydroFrame™ 10 HES	●	0.015	0.38	30 minutes	●	
HydroFrame™ 18 HES	●	0.0165	0.42	30 minutes	●	
HydroSoft® HES	●	0.015	0.38	30 minutes	●	
HydroSoft 18 HES	●	0.0165	0.42	10 minutes	●	
		0.021	0.53	30 minutes		
HES-10	●	0.015	0.38	5 minutes		●
HES-14	●	0.019	0.48	5 minutes		●
HES-18		0.021	0.53	5 minutes		●

INDICATIONS FOR USE

The HydroCoil Embolic System (HES) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

The device should only be used by physicians who have undergone pre-clinical training in all aspects of HES procedures as prescribed by MicroVention.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to: hematoma at the site of entry, vessel perforation, aneurysm rupture, parent artery occlusion, incomplete aneurysm filling, emboli, hemorrhage, ischemia, vasospasm, coil migration or misplacement, premature or difficult coil detachment, clot formation, revascularization, post-embolization syndrome, and neurological deficits including stroke and possibly death.

REQUIRED ADDITIONAL ITEMS

- MicroVention V-Grip® detachment controller
- Wire-reinforced microcatheter with 2 tip RO markers, appropriately sized
- Guide catheter compatible with microcatheter
- Steerable guidewires compatible with microcatheter
- 2 rotating hemostatic Y valves (RHV)
- 1 three-way stopcock
- MicroVention framing coils, size appropriate for aneurysm
- Sterile saline and/or lactated Ringer's injection
- Pressurized sterile saline drip
- Steam source for optional pre-softening of implant
- 1 one-way stopcock
- Stopwatch or timer

WARNINGS AND PRECAUTIONS

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

- The HES is sterile and non-pyrogenic unless the unit package is opened or damaged.
- The HES is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital, administrative and/or local government policy. Do not use if the packaging is breached or damaged.
- The HES must be delivered only through a wire-reinforced microcatheter with a PTFE inner surface coating. Damage to the device may occur and necessitate removal of both the HES and microcatheter from the patient.
- High quality, digital subtraction fluoroscopic road mapping is **mandatory** to achieve correct placement of the HES.
- Do not advance the V-Trak® delivery pusher with excessive force. Determine the cause of any unusual resistance, remove the HES and check for damage.
- Advance and retract the HES device slowly and smoothly. Remove the entire HES if excessive friction is noted. If excessive friction is noted with a second HES, check the microcatheter for damage or kinking.
- The coil must be properly positioned in the aneurysm within the specified reposition time. The reposition time is the time between introduction of the device into the microcatheter and the time of detachment. If the coil cannot be positioned and detached within this time, simultaneously remove the device and the microcatheter. Positioning the device outside of an aneurysm may diminish the reposition time.
- If repositioning is necessary, take special care to retract the coil under fluoroscopy in a one-to-one motion with the V-Trak® delivery pusher. If the coil does not move in a one-to-one motion with the V-Trak® delivery pusher, or if repositioning is difficult, the coil may have become stretched and could possibly break. Gently remove and discard the entire device.
- Due to the delicate nature of the HES coils, the tortuous vascular pathways that lead to certain aneurysms and vessels, and the varying morphologies of intracranial

- If a coil must be retrieved from the vasculature after detachment, do not attempt to withdraw the coil with a retrieval device, such as a snare, into the delivery catheter. This could damage the coil and result in device separation. Remove the coil, microcatheter, and any retrieval device from the vasculature simultaneously.
- If resistance is encountered while withdrawing a coil that is at an acute angle relative to the microcatheter tip, it is possible to avoid coil stretching or breaking by carefully repositioning the distal tip of the catheter at, or slightly inside, the ostium of the aneurysm. By doing so, the aneurysm and artery act to funnel the coil back into the microcatheter.
- Delivery of multiple HES coils is usually required to achieve the desired occlusion of some aneurysms or lesions. The desired procedural endpoint is angiographic occlusion. The filling properties of the HES coils facilitate angiographic occlusion and reduce the need to tightly pack.
- Always ensure that at least **two** MicroVention V-Grip® detachment controllers are available before starting a HES procedure.
- The HES cannot be detached with any power source other than a MicroVention V-Grip® detachment controller.
- Always advance an appropriately sized guidewire through the microcatheter after detaching the coil and removing the pusher to ensure that no part of the coil remains within the microcatheter.
- Do **NOT** place the V-Trak® delivery pusher on a bare metallic surface.
- Always handle the V-Trak® delivery pusher with surgical gloves.
- Do **NOT** use in conjunction with radio frequency (RF) devices.

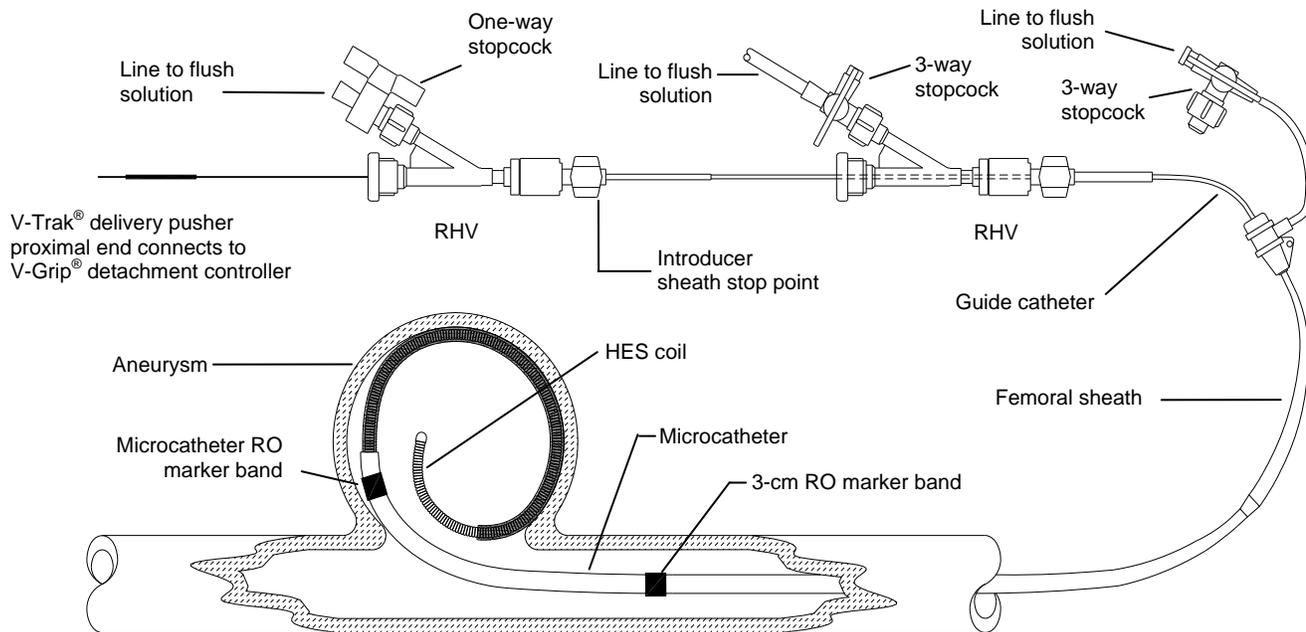


Diagram of HES Setup

CATHETERIZATION OF THE LESION

1. Refer to the set-up diagram.
2. Using standard interventional procedures, access the vessel with a guide catheter. The guide catheter should have an inner diameter (ID) large enough to allow for contrast injection while the microcatheter is in place. This will allow for fluoroscopic road mapping during the procedure.
3. Attach a rotating hemostatic valve (RHV) to the hub of the guiding catheter. Attach a 3-way stopcock to the side arm of the RHV and then connect a line for continuous infusion of flush solution.
4. Select a microcatheter with the appropriate inner diameter. After the microcatheter has been positioned inside the lesion, remove the guidewire.
5. Attach a second RHV to the hub of the microcatheter. Attach a 1-way stopcock to the sidearm of the second RHV and connect the flush solution line to the stopcock.
6. Open the stopcock to allow flush through microcatheter with sterile flush solution. To minimize the risk of thromboembolic complications, it is critical that a continuous

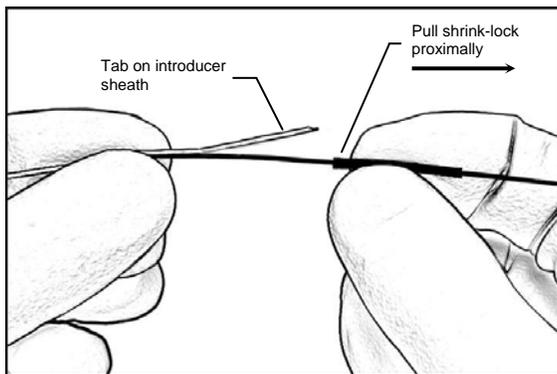
infusion of appropriate sterile flush solution be maintained into the guide catheter, the femoral sheath and the microcatheter.

COIL SIZE SELECTION

7. Perform fluoroscopic road mapping.
8. Measure and estimate the size of the lesion to be treated.
9. Select the appropriately sized coils. One or more framing coils should be used to establish the initial framework. The diameter of the first and second coils should never be less than the width of the aneurysm neck or the propensity for the coils to migrate may be increased. The diameter of the first HES helical coil should be 1-2 mm smaller than the initial basket coil.
10. Correct coil selection increases effectiveness and patient safety. Occlusive efficiency is, in part, a function of compaction and overall coil mass. In order to choose the optimum coil for any given lesion, examine the pre-treatment angiograms. The appropriate coil size should be chosen based upon angiographic assessment of the diameter of the parent vessel, aneurysm dome and aneurysm neck.

PREPARATION OF THE HES FOR DELIVERY

11. Remove the V-Grip® detachment controller from its protective packaging and place it within the sterile field. The V-Grip® detachment controller is packaged separately as a sterile device. **Do not use any power source other than the MicroVenton V-Grip® detachment controller to detach the coil. The V-Grip® detachment controller is intended to be used on one patient. Do not attempt to re-sterilize or otherwise re-use the V-Grip® detachment controller.**
12. Prior to using the device, remove the proximal end of the V-Trak® delivery pusher from the packaging hoop. Use care to avoid contaminating this end of the delivery pusher with foreign substances such as blood or contrast. Firmly insert the proximal end of the delivery pusher into the funnel section of the V-Grip® detachment controller. **Do not push the detachment button at this time.**
13. Wait three seconds and observe the indicator light on the detachment controller.
 - If the green light does not appear or if a red light appears, replace the device.
 - If the light turns green, then turns off at any time during the three-second observation, replace the device.
 - If the green light remains solid green for the entire three-second observation, continue using the device.
14. Hold the device just distal to the shrink-lock and pull the shrink-lock proximally to expose the tab on introducer sheath.



Pull Shrink Lock Proximally

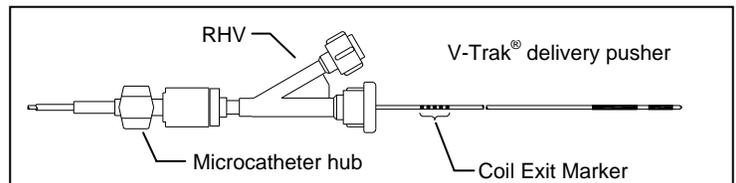
15. Slowly advance the HES implant out of the introducer sheath and inspect the coil for any irregularities or damage. **If any damage to the coil or V-Trak® delivery pusher is observed, DO NOT use the device.**
16. If necessary to soften the coil, advance it out of the distal end of the introducer sheath and immerse it in warm sterile saline or warm lactated Ringer's injection. Alternatively, hold it in a flow of steam until it curls, usually about five to ten seconds. When using steam, appropriate sterile technique should be used. In addition, the HES may be used without pre-softening.
17. With the distal end of the introducer sheath pointed downward and the implant still in the warm saline, warm lactated Ringer's injection or flow of steam, gently retract the implant back completely into the introducer sheath about 1 to 2 cm.

INTRODUCTION AND DEPLOYMENT OF THE HES

18. Open the RHV on the microcatheter just enough to accept the introducer sheath of the HES.
19. Insert the introducer sheath of the HES through the RHV. Seat the distal tip of the introducer sheath at the distal end of the microcatheter hub and close the RHV **lightly** around the introducer sheath to secure the RHV to the introducer. **Do not over-tighten the RHV around the introducer sheath. Excessive tightening could damage the device.**
20. Push the coil into the lumen of the microcatheter. Use caution to avoid catching the coil on the junction between the introducer sheath and the hub of the microcatheter. **Initiate timing using a stopwatch or timer at the moment the device enters the**

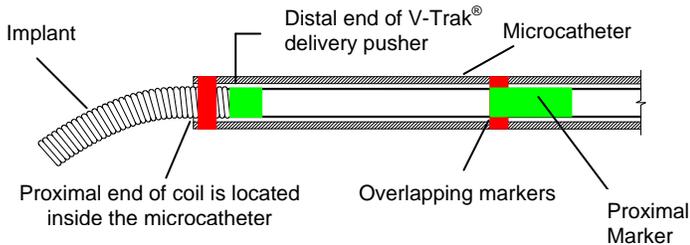
microcatheter. Detachment must occur within the specified reposition time.

21. Push the HES through the microcatheter until the proximal end of the V-Trak® delivery pusher meets the proximal end of the introducer sheath. Loosen the RHV. Retract the introducer sheath just out of the RHV. Close the RHV around the V-Trak® delivery pusher. Slide the introducer sheath completely off of the V-Trak® delivery pusher. Use care not to kink the delivery system. To prevent premature hydration of the HES, ensure that there is flow from the saline flush.
22. Discard the introducer sheath. The HES cannot be re-sheathed after introduction into the microcatheter.
23. Carefully advance the HES until the coil exit marker on the proximal end of the V-Trak® delivery pusher approaches the RHV on the hub of the microcatheter. At this time, fluoroscopic guidance must be initiated.



V-Trak® delivery pusher and Coil Exit Marker

24. Under fluoroscopic guidance, slowly advance the HES coil out the tip of the microcatheter. Continue to advance the HES coil into the lesion until optimal deployment is achieved. Reposition if necessary. If the coil size is not suitable, remove and replace with another device. If undesirable movement of the coil is observed under fluoroscopy following placement and prior to detachment, remove the coil and replace with another more appropriately sized coil. Movement of the coil may indicate that the coil could migrate once it is detached. **DO NOT** rotate the V-Trak® delivery pusher during or after delivery of the coil into the aneurysm. Rotating the HES V-Trak® delivery pusher may result in a stretched coil or premature detachment of the coil from the V-Trak® delivery pusher, which could result in coil migration. Angiographic assessment should also be performed prior to detachment to ensure that the coil mass is not protruding into the parent vessel.
25. Complete the deployment and any repositioning so that the coil will be detached within the reposition time specified in Table 1. After the specified time, the swelling of the hydrophilic polymer may prevent passage through the microcatheter and damage the coil. **If the coil cannot be properly positioned and detached within the specified time, simultaneously remove the device and the microcatheter.**
26. Advance the coil into the desired site until the radiopaque proximal marker on the delivery system is adjacent to the proximal marker on the microcatheter. The proximal end of the coil is inside the microcatheter. **To minimize the potential risk of aneurysm or vessel rupture, DO NOT advance the proximal marker on the delivery system distal to the proximal marker on the microcatheter.**



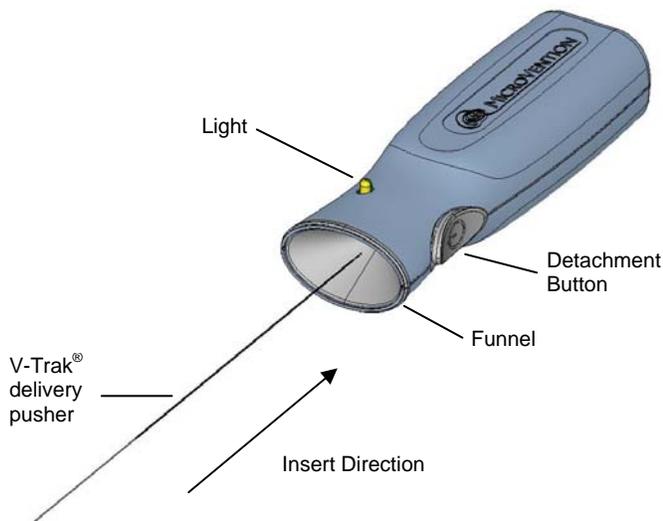
Position of Marker Bands for Detachment

To minimize the potential risk of aneurysm or vessel rupture, **DO NOT** advance the proximal marker on the delivery system distal to the proximal marker on the microcatheter.

27. Tighten the RHV to prevent movement of the coil.
28. Verify repeatedly that the distal shaft of the V-Trak[®] delivery pusher is not under stress before coil detachment. Axial compression or tension could cause the tip of the microcatheter to move during coil delivery. Catheter tip movement could cause the aneurysm or vessel to rupture.

DETACHMENT OF THE HES COIL

29. The V-Grip[®] detachment controller is pre-loaded with batteries and will activate when a MicroVention V-Trak[®] delivery pusher is properly connected. It is not necessary to push the button on the side of the V-Grip[®] detachment controller to activate it.
30. Verify that the RHV is firmly locked around the V-Trak[®] delivery pusher before attaching the V-Grip[®] detachment controller to ensure that the coil does not move during the connection process.
31. Although the V-Trak[®] delivery pusher's gold connectors are designed to be compatible with blood and contrast, every effort should be made to keep the connectors free of these items. If there appears to be blood or contrast on the connectors, wipe the connectors with sterile water or saline solution before connecting the V-Grip[®] detachment controller.
32. Connect the proximal end of the V-Trak[®] delivery pusher to the V-Grip[®] detachment controller by firmly inserting the proximal end of the V-Trak[®] delivery pusher into the funnel section of the V-Grip[®] detachment controller.

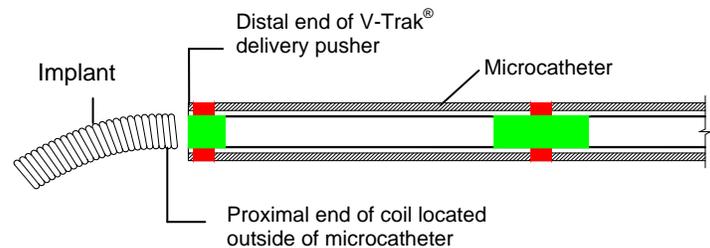


V-Grip[®] Detachment Controller

33. When the V-Grip[®] detachment controller is properly connected to the V-Trak[®] delivery pusher, a single audible tone will sound and the light will turn green to signal that it is ready to detach the coil. If the detachment button is not pushed within 30 seconds, the solid green light will slowly

flash green. Both flashing green and solid green lights indicate that the device is ready to detach. If the green light does not appear, check to ensure that the connection has been made. If the connection is correct and no green light appears, replace the V-Grip[®] detachment controller.

34. Verify the coil position before pushing the detachment button.
35. Push the detachment button. When the button is pushed, an audible tone will sound and the light will flash green.
36. At the end of the detachment cycle, three audible tones will sound and the light will flash yellow three times. This indicates that the detachment cycle is complete. If the coil does not detach during the detachment cycle, leave the V-Grip[®] detachment controller attached to the V-Trak[®] delivery pusher and attempt another detachment cycle when the light turns green.
37. The light will turn red after the number of detachment cycles specified on the V-Grip[®] labeling. **DO NOT** use the V-Grip[®] detachment controller if the light is red. Discard the V-Grip[®] detachment controller and replace it with a new one when the light is red.
38. Verify detachment of the coil by first loosening the RHV valve, then pulling back slowly on the delivery system and verifying that there is no coil movement. If the implant did not detach, do not attempt to detach it more than two additional times. If it does not detach after the third attempt, remove the delivery system.
39. After detachment has been confirmed, slowly advance the V-Trak[®] delivery pusher until the proximal end of the coil is outside the microcatheter. **Advancing the V-Trak[®] delivery pusher beyond the microcatheter tip once the coil has been detached involves risk of aneurysm or vessel rupture.**



After Detachment, Advance V-Trak[®] Delivery Pusher to Push Coil Outside the Microcatheter

40. After the coil is outside the microcatheter, pull the entire delivery system out of the microcatheter.
41. Verify the position of the coil angiographically through the guide catheter.
42. Prior to removing the microcatheter from the treatment site, place an appropriately sized guidewire completely through the microcatheter lumen to ensure that no part of the coil remains within the microcatheter.

The physician has the discretion to modify the coil deployment technique to accommodate the complexity and variation in embolization procedures. Any technique modifications must be consistent with the previously described procedures, warnings, precautions and patient safety information.

SPECIFICATIONS FOR V-GRIP[®] DETACHMENT CONTROLLER

- Output voltage: 8 VDC
- Cleaning, preventative inspection, and maintenance: The V-Grip[®] detachment controller is a single use device, preloaded with batteries, and packaged sterile. No cleaning, inspection, or maintenance is required. If the device does not perform as described in the Detachment section of these Instructions, discard the V-Grip[®] detachment controller and replace it with a new unit.
- The V-Grip[®] detachment controller is a single use device. It should not be cleaned, re-sterilized, or re-used.

- Batteries are pre-loaded into the V-Grip[®] detachment controller. Do not attempt to remove or replace the batteries prior to use.
- After use, dispose of the V-Grip[®] detachment controller in a manner consistent with local regulations.

Pulse Sequence: Plane Orientation:	T1-SE Parallel	T1-SE Perpendicular	GRE Parallel	GRE Perpendicular
Signal Void Size:	400 mm ²	70 mm ²	532 mm ²	196 mm ²

PACKAGING AND STORAGE

The HES is placed inside a protective, plastic dispenser hoop and packaged in a pouch and unit carton. The HES and dispenser hoop will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

A small round indicator label has been affixed to the HES package so that it is visible before the sterile barrier is breached. This indicator turns from yellow to red upon exposure to radiation and must be red in order to use the HES. If the indicator is yellow, DO NOT USE THE DEVICE.

The V-Grip[®] detachment controller is packaged separately in a protective pouch and carton. The V-Grip[®] detachment controller has been sterilized; it will remain sterile unless the pouch is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

A small round indicator label has been affixed to the V-Grip[®] detachment controller package so that it is visible before the sterile barrier is breached. This indicator turns from purple to green upon sterilization and must be green in order to use the V-Grip[®] detachment controller. If the indicator is purple, DO NOT USE THE DEVICE.

SHELF LIFE

See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

MR INFORMATION



The HydroCoil Embolic System (HES) implant has been determined to be **MR conditional** according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08.

Non-clinical testing demonstrated that the HES implant is **MR conditional**. A patient can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient field of 720 Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the HES implant produced a maximum temperature rise of 1.6°C during MRI performed for 15 minutes of scanning in the 3 Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system.

Therefore, the MRI-related heating experiments for the HES implant at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than 1.6°C.

Image Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the HES implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

MicroVention, Inc. recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation or equivalent organization.

MATERIALS

The HES does not contain latex or PVC materials.

SYMBOLS

The following symbols are used:



Lot Number



Catalog Number



Content



Sterilized Using Irradiation



Sterilized Using Ethylene Oxide



Do Not Reuse



Use-by Date



Date of Manufacture



Attention, Consult Accompanying Documents



CE Mark



Type BF Applied Part



Power ON and OFF



Manufacturer



Authorized European Representative



MR Conditional

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 restocked and makes no warranty, 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.

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MicroVention®, HydroCoil®, HydroSoft®, HyperSoft®, MicroPlex®, V-Grip® and V-Trak® are registered trademarks of MicroVention, Inc.

HydroFrame™ is a trademark of MicroVention, Inc.

This product is covered by one or more of the following US patents: 6,500,190, 6,602,261, and 6,878,384. Additional US and international patents are pending.



Manufacturer:

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Tel: 714.247.8000
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78100 Saint-Germain-en-Laye
France
Tel: +33 (1) 39 21 52 17
Fax: +33 (1) 39 21 16 01

PDXXXXX draft



ATTACHMENT 2
PRODUCT DRAWING

Pages 63 through 68 redacted for the following reasons:

(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

ATTACHMENT 3
RISK ANALYSIS

Pages 70 through 108 redacted for the following reasons:

(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

ATTACHMENT 4
BENCH TESTING

Pages 110 through 123 redacted for the following reasons:

(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

ATTACHMENT 5
ISO 13485 Certificate



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

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: HydroCoil Embolic System (HES)

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

(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)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: HydroCoil Embolic System (HES)

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
 1311 Valencia Avenue
 Tustin, California 92780
 U.S.A.

Contact: Laraine Pangelina

Predicate Device: HydroCoil Embolic System (K070656, K080666, K091641)

Device Description: The HES consists of implantable coil made of platinum alloy with inner hydrogel core. The helical-shaped implantable coil is available in various outer dimensions and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end of the pusher is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

Bench Test Summary:

Test	Result
Visual Inspection	Met same criteria as predicate
Dimensional Measurement	Met same criteria as predicate
Simulated Use	Met same criteria as predicate
Spring Constant	Met same criteria as predicate
Gel Expansion	Met same criteria as predicate
Weld Tensile	Met same criteria as predicate
Advancement / Retraction Force	Met same criteria as predicate

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

**Predicate / Subject
 Device Comparison:**

Feature	Predicate Device	Subject Device
Coil shape	Helical	Same
Implant diameter	2 mm – 10 mm	2 mm – 7 mm
Implant restrained length	1 cm – 30 cm	2 cm – 10 cm
Deliver pusher length	185 cm	Same
Main coil wire material	Platinum/Tungsten (92/8 %) alloy	Same
Coupler material	Platinum (90%) / iridium (10%)	Same
Adhesive material	Dymax 1128-AM-VT	Same
Implant to pusher material	Polyolefin Elastomer	Same
Stretch resistant filar material	Polyolefin Elastomer	Same
Gel material	Hydrophilic Copolymer	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser, pouch, carton	Same

**Summary of Substantial
 Equivalence:**

The HES coils that are the subject of this submission are substantially equivalent to the predicate device with regard to intended use, patient population, device design, materials, processes, and operating principal.



COVER SHEET MEMORANDUM

From: Reviewer Name ALEX BAILEY
Subject: 510(k) Number K112226/S1
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 with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age<=21		<input type="checkbox"/>	<input checked="" type="checkbox"/>

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K112226/S1

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. *The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)*

The sponsor identified their own previously cleared HydroCoil Embolic System as the predicate device.

- K070656 – HydroCoil® Embolic System (HES); consists of an implantable coil attached to a delivery system called a V-TRAK™ Delivery Pusher
 - K080666 – HydroSoft® and HydroSoft Plus Embolization Coil Systems with HES-HC-HS (10) Coils; these are embolization coils with an inner hydrogel core, and a V-Trak™ Delivery Pusher
 - K091641 – HydroCoil Embolic System (HydroSoft) and MicroPlex Coil System (HyperSoft); consists of an implant made of platinum alloy with an inner hydrogel core. The platinum alloy coils are designed in helical structures in various loop sizes and lengths and attached to a V-Trak™ delivery pusher via a polymer filament
2. *Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).*

Indications for use (IFU) for the new device states:

The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

The IFU for the new device is identical to each of the identified predicate devices (K091641, K080666, K070656).

Analysis:

The IFU is adequate.

3. *A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.*

Device description and modifications: A description of the device modifications were included on pages 20-22, and engineering drawings were provided in Attachment 2. Device modifications under this Special 510(k) include dimensional changes designed to improve filling attributes with repositioning time comparable to other commercialized HES coils. This is achieved by using an oval filar (0.0035" x 0.0015" outer diameter(OD)) instead of a round filar (0.002" OD) in the construction of the coil. The coil primary wind OD was also increased from 0.012" in the predicate device to 0.01525" in the new device.

The HES coils consist of an implant coil made of a platinum alloy (platinum/tungsten(92/8%)) with an inner hydrogel and elastomer core. The materials for the coil construction are the same as that previously cleared, including the main coil wire, couple material (platinum/iridium (90/10%)), UV curing adhesive (Dymax 1128-AM-VT), hydrogel coating (cross-linked copolymer of polyethylene glycol diacrylamide and acrylic acid), and polyofin elastomer. Bench testing included evaluation of the physical, mechanical, and functional performance of the device.

Biocompatibility: The subject device is made from the same material and using the same processes as those utilized in the manufacturing of the predicate devices. Biocompatibility studies were not repeated (pages 28-29).

Sterility and packaging: There are no changes to the packaging and sterilization method for the subject device as compared to the predicate device (page 29). Therefore no additional or repeat qualification, testing, or revalidation was performed.

Analysis:

The fundamental function to occlude aneurysms or blood vessels has not changed. I do not believe the device modifications change the underlying fundamental scientific technology. The intended use, materials used, design technology, operating principle, and manufacturing processes remain the same. The description of the device modifications is adequate.

4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and _____

Comparison information was provided on page 22 of the submission. As stated previously, changes include a modification in the shape of the filar; the predicate device has a round filar and the new device has an oval filar. According to the manufacturer, this modification is to improve the filling attributes of the device. The new device has the same IFU, intended use, principle of operation, materials, manufacturing processes, packaging, and sterilization method. The following is a comparison of features that have been modified:

Feature	Predicates (K070656, K080666, K091641)	Subject Device
Coil Filar OD	0.002" (round)	0.0035" x 0.0015" (oval)
Coil Primary Wind OD	0.012"	0.01525"

Coil Secondary Wind OD	2 mm – 10 mm	2 mm – 7 mm
Coil Restrained Length	1 cm – 30 cm	2 cm – 10 cm

Analysis:

The comparison is adequate. The design changes to the device should not effect safety or effectiveness.

5. A Design Control Activities Summary which includes:

- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
- c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The risk analysis and summary of design control activities for the new device was presented in pages 24-30. Complete reports of the risk analysis was submitted in Attachment 3, and protocols and a summary of results from the bench testing was submitted in Attachment 4.

The sponsor correctly identified the major risks with this design change: excessive friction or train wrecking when pushed through the introducer tube or microcatheter, snags or hitches during deployment, excessive tumbling of the implant, excessive microcatheter movement, loop prolapse into parent vessel, and excessive force placed on the aneurysm wall.

Based on the risk analysis, an identification of the necessary verification and/or validation activities were identified. Methods, tests, and acceptance criteria are comparable to testing done in predicate device.

Verification and validation testing was performed including:

- Visual inspection
- Simulated use (performed with both 0.021" and 0.015" microcatheters) at 10 minutes of repositioning time included:
 - Introduction
 - Tracking
 - Reposition/Deployment
 - Detachment
 - Overall Performance
- Spring constant
- Coil to coupler weld tensile strength
- Hydrogel diameter during expansion (at 50 minutes of expansion time)
- Advancement/retraction force (acceptance criteria of ≤0.145 lbf for both)

These tests validated the performance characterization of the device. Tests indicate that the *in vitro* behavior of the device is well-characterized within the design specifications (page 100).

Analysis:

The risk assessment they completed seemed adequate and identified necessary performance testing. Performance testing conducted (including methods and acceptance criteria) are comparable to those conducted with the predicate device. Performance testing is adequate. Please note that the sponsor indicated modifications were performed to improve filling attributes, which I believe is subjective and not quantifiable.

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).

A *Truthful and Accurate Statement* has been signed (page 9). A 510(k) Summary is included (pages 10-11). Indications for Use enclosure has been provided (page 12).

The submitted 510(k) Summary is inadequate because it does not describe the changes that were made to the predicate device that necessitated this 510(k) submission. As mentioned previously, device modifications included dimensional changes, for example the use of a oval filar instead of a round filar. These are not mentioned in the 510(k) summary. Furthermore, the bench test summary should include additional information on the types of testing that were performed, specifically what was evaluated during simulated use. The following formed the basis of an AI comment in the original submission:

You submitted a 510(k) summary for your device. However, we do not believe that this summary adequately describes your device. Please address the following:

- Your 510(k) summary does not describe the modifications that were made to the predicate device that necessitated this 510(k) submission. Please revise your 510(k) summary accordingly to include device modifications as compared to the predicate device, specifically a change in the coil filar outer diameter and shape.
- You included a summary of the bench tests that were performed to establish the equivalence of your new device to the predicate device. However, you do not state the specific testing that was performed during simulated use. Please revise your 510(k) summary to include a description of the parameters that were evaluated, such as introduction, tracking, reposition/deployment, detachment, and overall performance.

In S1, the sponsor provided a revised Summary of Safety and Effectiveness, which included the requested additional information. The sponsor's response is adequate.


(Reviewer's Signature)

9/20/11
(Date)

Comments

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: SE

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

Nichols, Karl *

From: Pangelina Laraine [laraine.pangelina@microvention.com]
To: Nichols, Karl *
Sent: Monday, September 19, 2011 3:11 PM
Subject: Read: K112226- AI letter

Your message was read on Monday, September 19, 2011 3:10:32 PM (GMT-05:00) Eastern Time (US & Canada).

Fife, Elizabeth *

From: Microsoft Exchange
To: 'laraine.pangelina@microvention.com'
Sent: Thursday, September 08, 2011 11:26 AM
Subject: Relayed: K112226 Holding

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'laraine.pangelina@microvention.com'

Subject: K112226 Holding

Sent by Microsoft Exchange Server 2007



COVER SHEET MEMORANDUM

From: Reviewer Name ALEX BAILEY
 Subject: 510(k) Number K112226
 To: The Record

Please list CTS decision code TH

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 (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

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)? For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			

Hoang, Quynh T.

From: Hoang, Quynh T.
Sent: Thursday, September 01, 2011 2:49 PM
To: 'laraine.pangelina@microvention.com'
CC: Bailey, Alexander
Subject: K112226 Additional information request from FDA
Attachments: K112226 Addtnl info request.pdf

Dear Ms. Pangelina:

Attached is FDA's request for additional information for K112226. Please contact Dr. Bailey, the team leader, if you have any questions.



K112226 Addtnl
info request.pd...

Regards.



DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation

K112226

Date: September 1, 2011
To: Microvention, Inc.
% Laraine Pangelina, Regulatory Affairs Project Manager
Phone: (714) 247-8150
Fax: (714) 247-8014
Email: laraine.pangelina@microvention.com

From: Alex M Bailey, Ph.D., Biomedical Engineer

Subject: Telephone hold for K112226 for Hydrocoil Embolic System (HES)

We have reviewed your Special 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; this document serves to notify you that we have placed the file on hold. To complete the review of your submission, we require that you respond to the following deficiency:

(b) (4)

(b)(4)

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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

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

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/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 me by email at alexander.bailey@fda.hhs.gov or by phone at (301) 796-1777. 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>.

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K112226

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. *The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)*

The sponsor identified their own previously cleared HydroCoil Embolic System as the predicate device.

- K070656 – HydroCoil® Embolic System (HES); *consists of an implantable coil attached to a delivery system called a V-TRAK™ Delivery Pusher*
 - K080666 – HydroSoft® and HydroSoft Plus Embolization Coil Systems with HES-HC-HS (10) Coils; *these are embolization coils with an inner hydrogel core, and a V-Trak™ Delivery Pusher*
 - K091641 – HydroCoil Embolic System (HydroSoft) and MicroPlex Coil System (HyperSoft); *consists of an implant made of platinum alloy with an inner hydrogel core. The platinum alloy coils are designed in helical structures in various loop sizes and lengths and attached to a V-Trak™ delivery pusher via a polymer filament*
2. *Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).*

Indications for use (IFU) for the new device states:

The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

The IFU for the new device is identical to each of the identified predicate devices (K091641, K080666, K070656).

Analysis:

The IFU is adequate.

3. *A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.*

Device description and modifications: A description of the device modifications were included on pages 20-22, and engineering drawings were provided in Attachment 2. Device modifications under this Special 510(k) include dimensional changes designed to improve filling attributes with repositioning time comparable to other commercialized HES coils. This is achieved by using an oval filar (0.0035" x 0.0015" outer diameter(OD)) instead of a round filar (0.002" OD) in the construction of the coil. The coil primary wind OD was also increased from 0.012" in the predicate device to 0.01525" in the new device.

The HES coils consist of an implant coil made of a platinum alloy (platinum/tungsten(92/8%)) with an inner hydrogel and elastomer core. The materials for the coil construction are the same as that previously cleared, including the main coil wire, couple material (platinum/iridium (90/10%)), UV curing adhesive (Dymax 1128-AM-VT), hydrogel coating (cross-linked copolymer of polyethylene glycol diacrylamide and acrylic acid), and polyofin elastomer. Bench testing included evaluation of the physical, mechanical, and functional performance of the device.

Biocompatibility: The subject device is made from the same material and using the same processes as those utilized in the manufacturing of the predicate devices. Biocompatibility studies were not repeated (pages 28-29).

Sterility and packaging: There are no changes to the packaging and sterilization method for the subject device as compared to the predicate device (page 29). Therefore no additional or repeat qualification, testing, or revalidation was performed.

Analysis:

The fundamental function to occlude aneurysms or blood vessels has not changed. I do not believe the device modifications change the underlying fundamental scientific technology. The intended use, materials used, design technology, operating principle, and manufacturing processes remain the same. The description of the device modifications is adequate.

4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and _____

Comparison information was provided on page 22 of the submission. As stated previously, changes include a modification in the shape of the filar; the predicate device has a round filar and the new device has an oval filar. According to the manufacturer, this modification is to improve the filling attributes of the device. The new device has the same IFU, intended use, principle of operation, materials, manufacturing processes, packaging, and sterilization method. The following is a comparison of features that have been modified:

Feature	Predicates (K070656, K080666, K091641)	Subject Device
Coil Filar OD	0.002" (round)	0.0035" x 0.0015" (oval)
Coil Primary Wind OD	0.012"	0.01525"

Coil Secondary Wind OD	2 mm – 10 mm	2 mm – 7 mm
Coil Restrained Length	1 cm – 30 cm	2 cm – 10 cm

Analysis:

The comparison is adequate. The design changes to the device should not effect safety or effectiveness.

5. A Design Control Activities Summary which includes:

- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
- c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The risk analysis and summary of design control activities for the new device was presented in pages 24-30. Complete reports of the risk analysis was submitted in Attachment 3, and protocols and a summary of results from the bench testing was submitted in Attachment 4.

The sponsor correctly identified the major risks with this design change: excessive friction or train wrecking when pushed through the introducer tube or microcatheter, snags or hitches during deployment, excessive tumbling of the implant, excessive microcatheter movement, loop prolapse into parent vessel, and excessive force placed on the aneurysm wall.

Based on the risk analysis, an identification of the necessary verification and/or validation activities were identified. Methods, tests, and acceptance criteria are comparable to testing done in predicate device.

Verification and validation testing was performed including:

- Visual inspection
- Simulated use (performed with both 0.021" and 0.015" microcatheters) at 10 minutes of repositioning time included:
 - Introduction
 - Tracking
 - Reposition/Deployment
 - Detachment
 - Overall Performance
- Spring constant
- Coil to coupler weld tensile strength
- Hydrogel diameter during expansion (at 50 minutes of expansion time)
- Advancement/retraction force (acceptance criteria of ≤0.145 lbf for both)

These tests validated the performance characterization of the device. Tests indicate that the *in vitro* behavior of the device is well-characterized within the design specifications (page 100).

Analysis:

The risk assessment they completed seemed adequate and identified necessary performance testing. Performance testing conducted (including methods and acceptance criteria) are comparable to those conducted with the predicate device. Performance testing is adequate. Please note that the sponsor indicated modifications were performed to improve filling attributes, which I believe is subjective and not quantifiable.

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).

A *Truthful and Accurate Statement* has been signed (page 9). A 510(k) Summary is included (pages 10-11). Indications for Use enclosure has been provided (page 12).

The submitted 510(k) Summary is inadequate because it does not describe the changes that were made to the predicate device that necessitated this 510(k) submission. As mentioned previously, device modifications included dimensional changes, for example the use of an oval filar instead of a round filar. These are not mentioned in the 510(k) summary. Furthermore, the bench test summary should include additional information on the types of testing that were performed, specifically what was evaluated during simulated use. The following will form the basis of an AI comment:

You submitted a 510(k) summary for your device. However, we do not believe that this summary adequately describes your device. Please address the following:

- Your 510(k) summary does not describe the modifications that were made to the predicate device that necessitated this 510(k) submission. Please revise your 510(k) summary accordingly to include device modifications as compared to the predicate device, specifically a change in the coil filar outer diameter and shape.
- You included a summary of the bench tests that were performed to establish the equivalence of your new device to the predicate device. However, you do not state the specific testing that was performed during simulated use. Please revise your 510(k) summary to include a description of the parameters that were evaluated, such as introduction, tracking, reposition/deployment, detachment, and overall performance.



(Reviewer's Signature)

8/29/11

(Date)

Comments

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No
1. Same Indication Statement?		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?		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		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%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:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

Nichols, Karl *

From: Microsoft Exchange
To: 'laraine.pangelina@microvention.com'
Sent: Thursday, August 04, 2011 5:12 PM
Subject: Relayed: K112226- ACK Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'laraine.pangelina@microvention.com'

Subject: K112226- ACK Letter

Sent by Microsoft Exchange Server 2007

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

(b) (4)

(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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or (301)-796-8118



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

September 19, 2011

MICROVENTION, INC.
1311 VALENCIA AVE
TUSTIN, CALIFORNIA 92780
ATTN: LARAIN PANGELINA

510k Number: K112226

Product: HYDROCOIL EMBOLIC SYSTEM (HES)

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.

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

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

Sincerely,

510(k) Staff

K112226/S1



September 1, 2011

FDA CDRH DMC

SEP 19 2011

Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002
Attn: Alex M. Bailey, Ph.D.

**Subject: 510(k) #K112226, HydroCoil Embolic System (HES) line extension
Response to Telephone Hold/Additional Information Request dated September 1, 2011**

Dear Dr. Bailey,

In response to the letter which you sent to me via email today, I have attached a revised copy of the Summary of Safety and Effectiveness for K112226 which includes the additional information as requested. The additional information requested in item (a) is located in the second paragraph of the Device Description section. The additional information requested in item (b) is located in the Bench Test Summary section.

The attached Summary of S&E is provided without "Confidential" at the bottom of the page, so it can be released via FOI. I believe this adequately addresses your request. If you have any question about the attachment, please contact me.

Best Regards,

Laraine Pangelina
Regulatory Affairs Project Manager
MicroVention, Inc.
Tel: (714) 247-8150
Fax: (714) 247-8014
laraine.pangelina@microvention.com

K-49

MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: HydroCoil Embolic System (HES)

Generic Name: Neurovascular Embolization Device, accessory

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California 92780
U.S.A.

Contact: Laraine Pangelina

Predicate Device: HydroCoil Embolic System (K070656, K080666, K091641)

Device Description: The HES consists of implantable coil made of platinum alloy with inner hydrogel core. The helical-shaped implantable coil is available in various outer dimensions and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end of the pusher is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

The RD11-006 HES is a line extension which is substantially the same as the predicate devices (K070656, K080666, K091641). The implantable coil portion of both the predicate and the subject device is constructed from platinum alloy wire. The RD11-006 implantable coil is constructed of an oval-shaped platinum alloy wire, whereas the predicate devices are constructed of a round platinum alloy wire. All other materials and design features are the same for both the predicate and subject devices.

Indications for Use: The HES is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

**MicroVention, Inc.
Special 510(k)
HydroCoil Embolic System (HES) – RD11-006 Line Extension**

Bench Test Summary:

Test	Result
Visual Inspection	Met same criteria as predicate
Dimensional Measurement	Met same criteria as predicate
Simulated Use <ul style="list-style-type: none"> • Introduction • Tracking • Reposition / Deployment • Detachment • Overall Performance 	Met same criteria as predicate
Spring Constant	Met same criteria as predicate
Gel Expansion	Met same criteria as predicate
Weld Tensile	Met same criteria as predicate
Advancement / Retraction Force	Met same criteria as predicate

Predicate / Subject Device Comparison:

Feature	Predicate Device	Subject Device
Coil shape	Helical	Same
Implant diameter	2 mm – 10 mm	2 mm – 7 mm
Implant restrained length	1 cm – 30 cm	2 cm – 10 cm
Deliver pusher length	185 cm	Same
Main coil wire material	Platinum/Tungsten (92/8 %) alloy	Same
Coupler material	Platinum (90%) / iridium (10%)	Same
Adhesive material	Dymax 1128-AM-VT	Same
Implant to pusher material	Polyolefin Elastomer	Same
Stretch resistant filar material	Polyolefin Elastomer	Same
Gel material	Hydrophilic Copolymer	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser, pouch, carton	Same

Summary of Substantial Equivalence:

The HES coils that are the subject of this submission are substantially equivalent to the predicate device with regard to intended use, patient population, device design, materials, processes, and operating principal.