JUN 30 2009

510(k) Summary

Trade Name:	HydroCoil Embolic System – HydroSoft MicroPlex Coil System - HyperSoft
Generic Name:	Neurovascular Embolization Device
Classification:	Class II, 21 CFR 882.5950
Submitted By:	MicroVention, Inc 75 Columbia Aliso Viejo, California U.S.A.
Contact:	Naomi Gong

Predicate Devices:

Number	Description	Clearance Date
K070656	HydroCoil Embolic System with the HES-HC-HS (10) [marketed under the HydroSoft name]	June 15, 2007
K0509054	MicroPlex Coil System and HydroCoil Embolic System	June 28, 2005

Device Description

The HydroSoft coils consist of an implant made of plantinum alloy with an inner hydrogel core. The coils are designed in helical structure in various loop sizes and lengths. 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. The implant segment detaches upon activation of the Detachment Controller.

The HyperSoft coils consist of an implant coil made of platinum alloy. The coils are designed in helical structure in various loop sizes and lengths. 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. The implant segment detaches upon activation of the Detachment Controller.

Indications For Use

The HydroSoft and HyperSoft coils are members of the HydroCoil Embolic System (HES) and MicroPlex Coil System (MCS). The intended use as stated in the product labeling is as follows:

The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/MCS 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.

Verification and Test Summary Table

Bench Testing	Result
Simulated Use	Met established criteria
Detachment Test	Met established criteria
Detachment Zone Tensile	Met established criteria
Advancement/Retraction Force	Met established criteria
Coil to Coupler Weld Tensile	Met established criteria
Spring Constant	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the HydroSoft and HyperSoft coils when compared with the predicate devices (K070656 and K050954)

The devices,

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

In summary, the HydroSoft and HyperSoft coils described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

MicroVention, Inc.
c/o Naomi Gong
Regulatory Affairs Project Manager
75 Columbia
Suite A
Aliso Viejo, CA 92656

Re: K091641
Trade/Device Name: MicroVention HydroCoil® Embolic System (HES) – HydroSoft Coils and MicroPlex® Coil System (MCS) – HyperSoft Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: June 3, 2009
Received: June 4, 2009

Dear Ms. Gong:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

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

Indications for Use

510(k) Number (if known): K091641

Device Name: HydroSoft Embolic System (HES) – HydroSoft Coils
MicroPlex Coil System (MCS) – HyperSoft Coils

Indications For Use:

The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/MCS 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 _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeff Toy

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

510(k) Number K091641

Page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

MicroVention, Inc.
c/o Naomi Gong
Regulatory Affairs Project Manager
75 Columbia
Suite A
Aliso Viejo, CA 92656

Re: K091641
Trade/Device Name: MicroVention HydroCoil® Embolic System (HES) – HydroSoft Coils and MicroPlex® Coil System (MCS) – HyperSoft Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG
Dated: June 3, 2009
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Sincerely yours,

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

Indications for Use

510(k) Number (if known): K091641

Device Name: HydroSoft Embolic System (HES) – HydroSoft Coils
MicroPlex Coil System (MCS) – HyperSoft Coils

Indications For Use:

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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeff Toy

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

510(k) Number K091641

Page 1 of 1

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

June 05, 2009

MICROVENTION, INC.
75 COLUMBIA SUITE A
ALISO VIEJO, CALIFORNIA 92656-1408
UNITED STATES
ATTN: NAOMI GONG

510k Number: K091641
Received: 6/4/2009
Product: HYDROCOIL EMBOLIC SYSTEM (HYDR

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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

K091641

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

June 3, 2009

RE: Special 510(k) Notification:
- HydroCoil Embolic System (HES) - HydroSoft Coils [Line Extension]
- MicroPlex Coil System (MCS) - Hypersoft Coils [Line Extension]

Predicate devices:
- HydroCoil Embolic System (HES) HydroSoft Coils (K070656)
- MicroPlex Coil System (MCS) HyperSoft Coils (K050954)

Classification: II
Regulation Number: 882.5950
Product Code: HCG
Classification Committee: Neurovascular Devices

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 HES-HydroSoft and MCS-HyperSoft Coils (Line Extension).

In this submission, we have added additional coil sizes of 1 mm diameter to our existing HES-HydroSoft and MCS-HyperSoft Coils.

The devices have been designed, developed, and tested according to the FDA special control guidance document: Vascular and Neurovascular Embolization Devices dated February 25, 2004.

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

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

K11

MicroVention, Inc. 75 Columbia, Suite A, Aliso Viejo, CA 92656 P: 949.461.3314 F: 949.461.3329 www.microvention.com

MICROVENTION
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ingenuity. for life.

Statement of Confidentiality: MicroVention, Inc. considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of MicroVention, Inc. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act. Thank you in advance for your consideration of our application. If there are any questions, please contact me at (949) 951-0592 or 282-3742.

Naomi Gong

June 3, 2009
Date

Naomi Gong
Regulatory Affairs Project Manager
Tel: (949) 461-3314 (ext. 1107)
Fax: (949) 349-1360
naomi.gong@microvention.com

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

June 3, 2009

RE: Special 510(k) Notification:
- HydroCoil Embolic System (HES) - HydroSoft Coils [Line Extension]
- MicroPlex Coil System (MCS) - Hypersoft Coils [Line Extension]

Predicate devices:
- HydroCoil Embolic System (HES) HydroSoft Coils (K070656)
- MicroPlex Coil System (MCS) HyperSoft Coils (K050954)

Classification: II
Regulation Number: 882.5950
Product Code: HCG
Classification Committee: Neurovascular Devices

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Naomi Gong
Regulatory Affairs Project Manager
Tel: (949) 461-3314 (ext. 1107)
Fax: (949) 349-1360
naomi.gong@microvention.com

Date

Table of Contents

1. FDA Forms

1.1. Medical Device User Fee Cover Sheet

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(6)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MICRO VENTION INC
75 COLUMBIA
ALISO VIEJO CA 92656
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
330773774

2. CONTACT NAME
Florin Truuvert

2.1 E-MAIL ADDRESS
florin.truuvert@microvention.com

2.2 TELEPHONE NUMBER (include Area code)
949-680-5061

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
949-349-1360

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] 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?
[X] 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.)
[ ] 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.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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).
[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(6) 10-Mar-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

1.2. CDRH Submission Coversheet FDA 3514

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
6/3/2009	(b)(6)	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
MicroVention, Inc.	2032493		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(949) 282-3742		
Street Address	FAX Number *(including area code)*		
75 Columbia, Suite A	(949) 349-1360		
City	State / Province	ZIP/Postal Code	Country
Aliso Viejo	CA	92656	USA
Contact Name			
Naomi Gong			
Contact Title	Contact E-mail Address		
Regulatory Affairs Project Manager	naomi.gong@microvention.com		

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

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

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

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

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

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify):*
  Additional sizes

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HCG	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K070656	1	HydroCoil Embolic System with HES-HC-HS (10)	1	MicroVention, Inc. 75 Columbia, Suite A Aliso Viejo, CA 92677
2	K059054	2	MicroPlex Coil System and HydroCoil Embolic System	2	MicroVention, Inc. 75 Columbia, Suite A Aliso Viejo, CA 92677
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Neurovascular Embolization Device

	Trade or Proprietary or Model Name for This Device		Model Number
1	HydroCoil Embolic System - HydroSoft	1	100101H2HS-V, 100102H2HS-V, 100103H2HS-V, 100104H2HS-V, 100105H2HS-V
2	MicroPlex Coil System- HyperSoft	2	100101HS-V, 100102HS-V, 100103HS-V, 100104HS-V, 100105HS-V, 100106HS-V
3		3	
4		4	
5		5	

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

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

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
HCG

C.F.R. Section *(if applicable)*
882.5950

Classification Panel
Neurological Devices

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/MCS 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.

FORM FDA 3514 (9/07) Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301)-796-8118 **PAGE 3 of 5 PAGES**

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 2032493	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: MicroVention, Inc.		Establishment Registration Number: 2032493
Division Name *(if applicable)*		Phone Number *(including area code)*: (949) 951-0592
Street Address: 75 Columbia, Suite A		FAX Number *(including area code)*: (949) 349-1360
City: Aliso Viejo	State / Province: CA	ZIP/Postal Code: 92656 / Country: USA
Contact Name: Naomi Gong	Contact Title: Regulatory Affairs Project Manager	Contact E-mail Address: naomi.gong@microvention.com

(b)(4)

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )
Street Address		FAX Number *(including area code)*: ( )
City	State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					

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

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

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

1.3. Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(k)]

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

_____
(Signature)

Naomi Gong_____
(Typed Name)

_____
(Date)

1.4. 510(k) Summary

510(k) Summary

Trade Name:	HydroCoil Embolic System – HydroSoft MicroPlex Coil System - HyperSoft
Generic Name:	Neurovascular Embolization Device
Classification:	Class II, 21 CFR 882.5950
Submitted By:	MicroVention, Inc 75 Columbia Aliso Viejo, California U.S.A.
Contact:	Naomi Gong

Predicate Devices:

Number	Description	Clearance Date
K070656	HydroCoil Embolic System with the HES-HC-HS (10) [marketed under the HydroSoft name]	June 15, 2007
K0509054	MicroPlex Coil System and HydroCoil Embolic System	June 28, 2005

Device Description

The HydroSoft coils consist of an implant made of plantinum alloy with an inner hydrogel core. The coils are designed in helical structure in various loop sizes and lengths. The coil is attached to a V-*Trak*^{TM} 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*^{TM} Detachment Controller. The implant segment detaches upon activation of the Detachment Controller.

The HyperSoft coils consist of an implant coil made of platinum alloy. The coils are designed in helical structure in various loop sizes and lengths. The coil is attached to a V-*Trak*^{TM} 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*^{TM} Detachment Controller. The implant segment detaches upon activation of the Detachment Controller.

Indications For Use

The HydroSoft and HyperSoft coils are members of the HydroCoil Embolic System (HES) and MicroPlex Coil System (MCS). The intended use as stated in the product labeling is as follows:

The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/MCS 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.

Verification and Test Summary Table

Bench Testing	Result
Simulated Use	Met established criteria
Detachment Test	Met established criteria
Detachment Zone Tensile	Met established criteria
Advancement/Retraction Force	Met established criteria
Coil to Coupler Weld Tensile	Met established criteria
Spring Constant	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the HydroSoft and HyperSoft coils when compared with the predicate devices (K070656 and K050954)

The devices,

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

In summary, the HydroSoft and HyperSoft coils described in this submission is, in our opinion, substantially equivalent to the predicate device.

1.5. Indication for Use

Indications for Use

510(k) Number (if known):_____

Device Name: HydroSoft Embolic System (HES) – HydroSoft Coils
MicroPlex Coil System (MCS) – HyperSoft Coils

Indications For Use:

The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/MCS 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 _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

1.6. Form FDA 3674

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

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

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

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER

Naomi Gong

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

June 2, 2009

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

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

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

(T) +1 (949) 951-0592
(F) +1 (949) 349-1360

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(*Attach extra pages as necessary*)

HydroCoil Embolic System - HydroSoft	
MicroPlex Coil System - HyperSoft	

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (*If number previously assigned*)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT/INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES
(*See instructions for additional information and explanation*)

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN # 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
(*Attach extra pages as necessary*)

NCT Number(s)

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (SIGN)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN #11
	Naomi Gong Regulatory Affairs Project Manager
13. ADDRESS (*Number, Street, State, and Zip Code*) *(of person identified in #11 & 12)*	14. TELEPHONE AND FAX NUMBER (*Include Area Code*)
75 Columbia, Suite A Aliso Viejo, CA 92656	(T) +1 (949) 951-0592 (F) +1 (949) 349-1360
15. DATE OF CERTIFICATION June 3, 2009	

Paperwork Reduction Act Statement

Public Reporting Burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

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

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

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

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

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. Name of Sponsor/Applicant/Submitter - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date - This is the date of the application/submission which the certification accompanies.

3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. Product Information - For Drugs/Biologics: Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/ submission. Include all available names by which the product is known.
For Devices: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. Type of Application/Submission - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. Certification - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

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

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. National Clinical Trial (NCT) Numbers - If you have checked Box C in # 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. Signature of Sponsor/Applicant/Submitter or an Authorized Representative - The person signing the certification must sign in this field.

12. Name and Title of Person Who Signed in #11. - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/ submitter.

13. & 14. & 15. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 12. Provide the date the certification is signed. This date may be different from the date provided in #2.

1.7. Form FDA 3654

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

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-1

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Vascular and Neurovascular Embolization Devices Dated February 25, 2004.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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.

1.8. Declaration of Conformity

Declaration of Conformity With Design Controls

HydroCoil Embolic System – HydroSoft
MicroPlex Coil System – HyperSoft

Verification Activities:

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

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

5/28/2009
Date

==========

Manufacturing Facility:

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

Naomi Gong
Regulatory Affairs Project Manager

5/28/2009
Date

1.9. Design Control Activities Summary

HES- HydroSoft Coils - Design Control Activities Summary

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

MCS-HyperSoft Coils - Design Control Activities Summary

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

2. Executive Summary

The HES-HydroSoft and MCS-HyperSoft coils are 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.

Two configurations of coils are being submitted in this application:

- HydroCoil Embolic System (HES)-HydroSoft
- MicroPlex Coil System (MCS)-HyperSoft

Additional coil sizes are being added to both of the HES-HydroSoft and MCS-HyperSoft coils that were cleared via premarket notifications, K070656 and K050954, respectively. *Note: The HES-HC-HS (10) coils cleared under 510(k) K07656 have subsequently been commercialized under the name of HES-HydroSoft.*

We are adding the following configurations to provide more choices for the physician:

- HES- HydroSoft: 1mm diameter coil sizes
- MCS-HyperSoft: 1mm diameter coil sizes

The HES-HydroSoft coils consist of an implant coil made of bare platinum alloy (Platinum/Tungsten) with an inner hydrogel core. The coil is attached to a V-*Trak*^{TM} delivery pusher via a polyolefin elastomer material. The delivery pusher contains radiopaque positioning markers at the distal end. The proximal end is inserted into a hand held battery powered V-*Grip*^{TM} Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implant segment. The V-*Grip* is packaged and sold separately. The MCS-HyperSoft coils are similar to the HES-HydroSoft coils with the exception of no inner hydrogel core.

For both coil configurations, there is no change to the design technology and the principal of operation. The *in vitro* testing covered the physical, mechanical, and functional performance of the coils. These tests validated the performance characterization of these coils. The combined conclusion from these tests demonstrates that the *in vitro* behavior of these coils is well characterized within the design specifications.

We use the same material that is used in the existing configurations of the HES-HydroSoft and MCS-Hypersoft coils (K07656 and K050954). The biocompatibility study according to ISO10993-1 conducted on the coils provides assurance that the coils have a safe biocompatibility profile and is safe to use as long-term implantable device.

There is no change to the packaging and sterilization method. The coils are packaged in the same packaging configuration as the existing coils. The product is sterilized using the same gamma sterilization cycle. Lastly, there is no change to the intended use and Instructions for Use.

3. Device Name

The device trade names and common/classification names are:

Device Trade Name	HydroCoil Embolic System (HES) - HydroSoft MicroPlex Coil System (MCS) – HyperSoft
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

4. Address and Registration Number

The address and registration number of the manufacturer and sterilization sites for the Detachment Controller is:

Manufacturer	MicroVention, Inc. 75 Columbia Aliso Viejo, California U.S.A
Establishment Registration No.	MicroVention 2032493
Contact	Naomi Gong Regulatory Affairs Project Manager 75 Columbia Aliso Viejo, California U.S.A. Phone: (949) 282-3742 Fax: (949) 349-1360
Sterilization Site	Sterigenics (Gamma radiation) 344 Bonnie Circle Corona, CA 92880 FDA Registration No = 2029275

5. Device Class

Neurovascular Embolization Device is classified as Class II, HCG. The product has been designed, developed and tested using the FDA Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices dated February 25, 2004.

6. Predicate Device Information

K070656, MicroVention Inc., HydroCoil Embolic System- HES-HC-HS (10)

K050954, MicroVention, Inc., MicroPlex Coil System and HydroCoil Embolic System

7. Labeling and Intended Use

Draft labels and Instructions For Use are provided in Attachment 1.

Both configurations of HES-HydroSoft and MCS-HyperSoft have the same indications for use as the predicate devices.

Intended Use

The intended use as stated in the product labeling is as follows:

> *The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES/MCS 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.*

8. Device Description

8.1. HES-HydroSoft:

Similar to the existing HES- HydroSoft, the additional coils are designed in helical structure. The HydroSoft coils consist of an implant coil made of platinum alloy with an inner hydrogel core.

Similar to the existing devices, the implant coil is attached to a V-Trak™ delivery pusher via the polyolefin elastomer. The delivery pusher is a variable stiffness, stainless steel and tapered mandrel. The pusher consists of a radiopaque positioning markers that is inserted into a hand held battery powered *V-Grip* Detachment Controller.

8.2. MCS-HyperSoft:

Similar to the existing MCS- HyperSoft, the additional coils are designed in a helical structure and consist of an implant coil made from bare platinum alloy.

Similar to the existing devices, the implant coil is attached to a V-Trak™ delivery pusher via the polyolefin elastomer. The delivery pusher is a variable stiffness, stainless steel and tapered mandrel. The pusher consists of a radiopaque positioning markers that is inserted into a hand held battery powered *V-Grip* Detachment Controller.

8.3. For both configurations of coils, the *V-Grip* is packaged and sold separately as a sterile device for single patient only. There is no change to the delivery pusher, the *V-Grip* or the operating principle.

9. Device Configurations and Dimensions

9.1. HES-HydroSoft:

The HES-HydroSoft coils are designed in a helical configuration and have the same design, materials, construction, and manufacturing processing as the predicate device (K070656).

The additional sizes of the HES-HydroSoft coils are available in the following models:

HES-HydroSoft

Catalogue Number	Coil Diameter (mm)	Coil Length (cm)
100101H2HS-V	1	1
100102H2HS-V	1	2
100103H2HS-V	1	3
100104H2HS-V	1	4
100105H2HS-V	1	5

9.2. MCS-HyperSoft:

The MCS-HyperSoft coils are designed in a helical configuration and have the same design, materials, construction, and manufacturing processing as the predicate device (K050954).

The additional sizes of the MCS-HyperSoft coils are available in the following models:

MCS-HyperSoft

Catalogue Number	Coil Diameter (mm)	Coil Length (cm)
100101HS-V	1	1
100102HS-V	1	2
100103HS-V	1	3
100104HS-V	1	4
100105HS-V	1	5
100106HS-V	1	6

Accessory

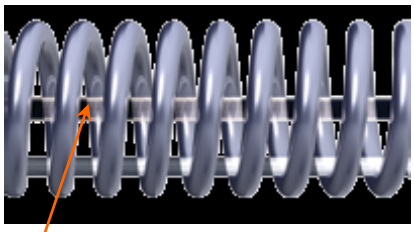
Accessory	Catalogue Number
V-*Grip* Detachment Controller	VG501

10. Design Description

10.1. HES-HydroSoft

The HES-HydroSoft coils are made of a platinum alloy (Pt/W: 92/8) in a helical configuration with an inner hydrogel core.

In this submission, we are simply adding the 1mm size coils as a line extension to the HES-HydroSoft coils with lengths from 1 to 5 cm. The added coils are compatible with 10-system microcatheters as it is for the predicate devices.

HES- HydroSoft


10.2. MCS-HyperSoft:

The MCS-HyperSoft coils are made of platinum alloy (Pt/W: 92/8) with a helical configuration. These MCS-HyperSoft are bare platinum coils.

In this submission, we are simply adding the 1mm size coils as a line extension to the MCS-HyperSoft coils with lengths from 1 to 6 cm. The added coils are compatible with 10-system microcatheters as it is for the predicate devices.

MCS-HyperSoft


10.3. There is no change to the intended use. There is no change to the embolization coil materials and delivery pusher. The deployment method remains unchanged. It uses the same hand held battery powered *V-Grip* Detachment Controller. Additionally, there is no change in the packaging and sterilization methods.

Sample product drawings for the HES-HydroSoft and MCS-HyperSoft coils are provided in Attachment 2.

11. Technological Characteristics Comparison

11.1. HES-HydroSoft Coils

The following table compares the technological characteristics of the existing HES-HydroSoft coils (K070656) with the additional models presented in this 510(k) submission.

HES-HydroSoft Comparison Table

	Existing HES-HydroSoft	HES-HydroSoft
(b)(4)	(b)(4)	

11.2. MCS-HyperSoft Coils

The following table compares the technological characteristics of the existing MCS-HyperSoft coils (K050954) with the additional models presented in this 510(k) submission.

MCS-HyperSoft Comparison Table

	Existing MCS-HyperSoft (K050954)	**MCS-HyperSoft** (line extension)
(b)(4)	(b)(4)	

12. Design Control and Risk Management Processes

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

Copies of the Design and Development and Risk Management Procedures, and the Detachment Controller Risk document are included.

The Risk Management Files for the HES-Hydrosoft and MicroPlex Coils are presented in a previous format, however, these risk documents remain applicable and identify the risks and levels necessary for the risk management process.

Attachment 3 – QP 4.1, Quality Procedure Design and Development Process
Attachment 4 – QP 4.8, Quality Assurance Risk Management Procedure
Attachment 5 – RA02001, Risk Management File, HydroCoil Embolic System (HES)
RA03001, Risk Management File, MicroPlex Coil System (MCS)

13. List of Voluntary Standards

The HES-HydroSoft and MCS-HyperSoft coils were designed, developed and tested using the applicable requirement of the following 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	2001
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 DIN 980	Graphical Symbol used in Labeling of Medical Devices	2003
ISO 11607 -1, -2	Packaging for Terminally Sterilized Medical Devices	2006
EN 1041	"Terminology, Symbols and Information Supplied with Devices."	1998

14. In-Vitro/Bench Verification

14.1. HES-HydroSoft Coils

For the HES-HydroSoft coils, we are adding coil sizes of 1mm diameter. In previously cleared 510(k) – K070656, the coils were tested and verified for simulated use, detachment test, detachment zone tensile test, advancement/retraction force, coupler/coil tensile strength, spring constant, and hydrogel expanded diameter.

With the addition of the 1mm coils, testing was conducted on 20 samples of 1mm x 1cm (smallest) to 1mm x 5 cm (largest) to represent the range of coils. Samples underwent the following tests:

Simulated Use: Preparation, Introduction, Tracking, Repositioning, Detachment, and Stability.

As presented in the test results below, all test samples met the established design specification criteria.

14.1.1. Simulated Use

(b)(4)

(b)(4)

To verify that the HES-HydroSoft coils met the established performance specifications in a clinically simulated environment, Microvention has tested a total of 60 to 100 samples (including the 20 samples of 1mm coils). Simulated use testing was completed and results presented in the table below using a range of 0.015" and 0.021" microcatheters.

Simulated Use Results (TM 092)	
	(b)(4)
Average	(b)(4)
Std. Dev.	
Minimum	
N	
Specification	
Pass/Fail	

14.1.2. Detachment Testing (TM092) and Reposition Time

The detachment testing of the coil implant was performed after 30 minutes of repositioning per TM092. Test results are presented below:

Detachment	
Detachment rating of 5	60 devices
Detachment rating of 4	No devices
Detachment rating of 3	No devices
Detachment rating of less than 3	No devices
N	60
Specification	≥ 3
Pass/Fail	Pass
Reposition Time	
All devices met 30 minute reposition time without gel sheer	Pass

14.1.3. Detachment Zone Tensile Strength

Detachment zone tensile strength was tested and measured after simulated use per TM 125. The test results are provided below:

(b)(4)

(b)(4)

14.1.4. Advancement and Retraction Force

Advancement/Retraction force testing represents the maximum force required to advance and retract the coil through the microcatheter after 30 minutes per TM093. Test results are presented below:

	Advancement		Retraction	
Coil Size	(b)(4)			
Average				
Std. Dev.				
Maximum				
N				
Specification				
Pass/Fail	Pass	Pass	Pass	Pass

14.1.5. Spring Constant

The spring constant force of the coil was measured after simulated use testing per TM 101. Results are presented in the table below:

Spring Constant	
Average	(b)(4)
Standard Deviation	
Minimum	
Maximum	
N	
Specification	
Pass/Fail	Pass

14.1.6. Coil to Coupler Weld Tensile Strength

The coil/coupler weld tensile strength was tested and measured per TM125. Results are provided in the table below:

Weld Tensile	2 x 1	6 x 8
Average	(b)(4)	
Standard Deviation		
Minimum		
N		
Specification		
Pass/Fail	Pass	Pass

14.1.7. Expanded Diameter of Hydrogel

The expanded diameter of the hydrogel post hydration was measured at 60 minutes per TM 114. The test results are provided below

Gel Diameter	2 x 1	6 x 8
Average	(b)(4)	
Standard Deviation		
Minimum		
Maximum	(b)(4)	
N		
Specification		
Pass/Fail	Pass	Pass

14.1.8. For the HES-HydroSoft coils, the in-vitro/bench test results are documented in TR 06-052 in Attachment 6.

14.2. MCS-HyperSoft Coils

For the MCS-HyperSoft coils, we are adding coil sizes of 1mm diameter. In previously cleared 510(k) – K0509054, the coils were tested and verified for simulated use, detachment test, detachment zone tensile test, advancement/retraction force, coupler/coil tensile strength, and spring constant.

With the addition of the 1mm coils, testing was conducted on 20 samples of 1mm x 1cm (smallest) to 1mm x 6 cm (largest) to represent the range of coils. Samples underwent the following tests:

Simulated Use: Introduction, Tracking, Repositioning, Stability, Detachment, and Overall.

As presented in the test results below, all test samples met the established design specification criteria.

14.2.1. Simulated Use

***In-Vitro* "Simulated Use" Test in Simulated Intra-Cranial Silicone Aneurysms:** (Refer to Section 14.1.1 for simulated use model description and diagram.)

To verify that the MCS-HyperSoft coils met the established performance specifications in a clinically simulated environment, Microvention has tested a total of 20 samples of 1 mm coils. Simulated use testing was completed and results presented in the table below using a range of 0.015" and 0.021" microcatheters.

Simulated Use Results (TM 054)					
	Introduction	Tracking	Repositioning	Stability	Overall
Average	5	5	5	5	5
Std. Dev.	0	0	0	0	0
Minimum	5	5	5	5	5
N	20	20	20	20	20
Specification	≥3	≥3	≥3	≥3	≥3
Pass/Fail	Pass	Pass	Pass	Pass	Pass

Advancement and Retraction force results were measured by the tracking portion of simulated use testing. A score of 5 is given for negligible levels of resistance to push the implant into the aneurysm.

14.2.2. Detachment Testing

The detachment testing of the coil implant was performed per TM054. Test results are presented below:

Detachment	
Average	5
Std. Dev.	0.4
Minimum	3
N	300
Specification	≥ 3
Pass/Fail	Pass

14.2.3. Detachment Zone Tensile Strength

Detachment zone tensile strength was tested and measured after simulated use per TM 125. The test results are provided below:

Detachment zone tensile strength	
Average	0.166 lb
Std. Dev.	0.025 lb
Minimum	0.112 lb
N	72
Specification	≥ 0.08 lb
Pass/Fail	Pass

14.2.4. Spring Constant

The spring constant force of the coil was measured after simulated use testing per TM 101. Results are presented in the table below:

Spring Constant	
Average	10.41 oz/in
Standard Deviation	1.90 oz/in
Minimum	8.44 oz/in
Maximum	13.24 oz/in
N	5
Specification	> 0.09 oz/in
Pass/Fail	Pass

14.2.5. Coil to Coupler Weld Tensile Strength

The coil/coupler (marker band) weld tensile strength was tested and measured per TM058. Results are provided in the table below:

Weld Tensile	Group 1	Group 2	Group 3
Average	0.171 lb	0.161 lb	0.156 lb
Standard Deviation	0.025 lb	0.023 lb	0.019 lb
Minimum	0.124 lb	0.134 lb	0.130 lb
N	10	10	10
Specification	> 0.08 lb	> 0.08 lb	> 0.08 lb
Pass/Fail	Pass	Pass	Pass

14.2.6. For the MCS-HyperSoft coils, the in-vitro/bench test results are documented in TR09-095 in Attachment 6.

15. Packaging, Sterilization, and Shelf Life

As the existing HES-HydroSoft and MCS-HyperSoft coils, these 1 mm coils are packaged and sterilized by Gamma Radiation. The sterilization method remains unchanged. Additionally, no changes in materials or other design attributes have been made to the 1mm coils that would warrant additional packaging qualifications or sterilization revalidation.

Packaging Configuration

Packaging	Existing HES-HydroSoft & MCS-HyperSoft	HES-HydroSoft MCS-HyperSoft (line extension)
Material	1. Introducer Sheath: HDPE Petrothene 2. Dispenser Coil: Polyethylene 3. Pouch (MCS): Polyester/Tyvek Pouch (HES): Polyester 4. Carton Box: Bleached Sulfate	1. Same 2. Same 3. Same 4. Same
Package Configuration	In plastic dispenser packaging, with introducer in place for introduction of coil into microcatheter.	Same
Method of Supplying	Sterile and single use. Coil attached to the pusher (delivery) wire, introducer over coil, in plastic packaging hoop.	Same
Method of Sterilization	Gamma Radiation	Same

No material changes have been made to warrant repeating of shelf-life studies on the 1mm size coils of HES-HydroSoft and MCS-HyperSoft. The shelf life will remain the same as the existing coils.

16. Biocompatibility

Biocompatibility studies were not repeated as the HES-HydroSoft and MCS-HyperSoft line extension coils as they are made from the same material that is being utilized in the fabrication of existing predicate coils. The biological safety of the coils has previously been verified in accordance with the ISO10993-1, Biological Evaluation of Medical Devices by independent laboratories, Biological Test Center, Toxikon, and AppTec. The tables below summarize the tests conducted and the results provide assurance that the implant (permanent, blood contact) and the V-Trak delivery pusher (≤ 24 hrs, blood contact) have a safe biocompatibility profile.

HES-HydroSoft

Implant Segment - Biocompatibility Summary

Cytotoxity	Requirement	Results
MEM Elution Test	Meet ISO 10993-5	Passed AppTec Report 52300
ISO Cell Culture Agar Overlay	Meet ISO 10993-5	Passed AppTec Report 52301
Sensitization	**Requirement**	**Results**
Sensitization-Guinea Pig Maximization Test	Meet ISO 10993-10	Passed AppTec Report 52303
Irriation	**Requirement**	**Results**
ISO Intracutaneous Reactivity Evaluation Test	Meet ISO 10993-10	Passed AppTec Report 52303
Hemocompatibility	**Requirement**	**Results**
Hemolysis	Meet ISO 10993-4	Passed AppTec Report 52308
Prothrombin Time Assay - ISO	Meet ISO 10993-4	Passed AppTec Report 52306
Systemic Toxicity	**Requirement**	**Results**
Systemic toxicity (IV injection)	Meet ISO 10993-11	Passed AppTec Report 52304
Rabbit Pyrogen Test (material mediated)	Meet ISO 10993-11	Passed Toxikon Report 07-0750-G1
Genetic Toxicology	**Requirement**	**Results**
Bacteria Reverse Mutation Assay (Ames Test)	Meet ISO 10993-3	Passed BioReliance Report AB24EM.502201.BTL
Intramuscular Implantation	**Requirement**	**Results**
7-day Muscle Implantation	Meet ISO 10993-6	Passed AppTec Report 30278
13-week Intramuscular Implantation Test	Meet ISO 10993-6	Passed AppTec Report 30279
26-week Intramuscular Implantation Test	Meet ISO 10993-6	Passed AppTec Report 30280

MCS- HyperSoft

Implantable Segment - Biocompatibility Summary

Cytotoxity	Requirement	Results
MEM Elution Test	Meet ISO 10993-5	Passed BTC Report P0904004
ISO Cell Culture Agar Overlay	Meet ISO 10993-5	Passed BTC Report P0904004
Sensitization	**Requirement**	**Results**
Sensitization-Guinea Pig Maximization Test	Meet ISO 10993-10	Passed BTC Report P0904018

Irriation	Requirement	Results
ISO Intracutaneous Reactivity Evaluation Test	Meet ISO 10993-10	Passed BTC Report P0904007
Hemocompatibility	**Requirement**	**Results**
Hemolysis	Meet ISO 10993-4	Passed BTC Report P0904008
Prothrombin Time Assay - ISO	Meet ISO 10993-4	Passed Toxikon Report 04-4396-G1
Systemic Toxicity	**Requirement**	**Results**
Systemic toxicity (IV injection)	Meet ISO 10993-11	Passed BTC Report P0904006
Rabbit Pyrogen Test (material mediated)	Meet ISO 10993-11	Passed Toxikon Report 07-0750-G1
Genetic Toxicology	**Requirement**	**Results**
Bacteria Reverse Mutation Assay (Ames Test)	Meet ISO 10993-3	Passed BioReliance Report AA98UY.502201.BTL
Intramuscular Implantation	**Requirement**	**Results**
7-day Muscle Implantation	Meet ISO 10993-6	Passed BTC Report P0904009
13-week Intramuscular Implantation Test	Meet ISO 10993-6	Passed Toxikon Report 04-4441-G2
26-week Intramuscular Implantation Test	Meet ISO 10993-6	Passed Toxikon Report 04-4441-G1

Delivery Pusher Segment

Biocompatibility Summary (for HES-HydroSoft and MCS-HyperSoft)

Cytotoxity	Requirement	Results
MEM Elution Test	Meet ISO 10993-5	Passed AppTec Report 140320I
ISO Cell Culture Agar Overlay	Meet ISO 10993-5	Passed AppTec Report140150H
Sensitization	**Requirement**	**Results**
Sensitization-Guinea Pig Maximization Test	Meet ISO 10993-10	Passed Toxikon Report 05-3829-G1
Irriation	**Requirement**	**Results**
ISO Intracutaneous Reactivity Evaluation Test	Meet ISO 10993-10	Passed AppTec Report 910700M
Hemocompatibility	**Requirement**	**Results**
Hemolysis	Meet ISO 10993-4	Passed AppTec Report 150100F
Prothrombin Time Assay - ISO	Meet ISO 10993-4	Passed Toxikon Report 05-4219-G1
Systemic Toxicity	**Requirement**	**Results**
Systemic toxicity (IV injection)	Meet ISO 10993-11	Passed AppTec Report 901770L
Rabbit Pyrogen Test (material mediated)	Meet ISO 10993-11	Passed AppTec Report 900770L

17. Sterilization

Gamma Sterilization Process

The HES-HydroSoft and MCS-HyperSoft coils are sold sterile, for single use and single patient only. As a part of the final assembly and packaging in Aliso Viejo, California, MicroVention will be sterilizing these coils in the same manner as other MicroVention sterile coil products. The system is currently sterilized using Gamma Radiation 25-40 kGy.

The Sterigenics is the contract manufacturer located in Corona, California and is an FDA registered establishment.

The validation and routine Gamma sterilization is performed in accordance with the requirement of the ANSI/AAMI/ISO11137-1; 2006, Medical Devices- Sterilization of Health Care Products Radiation Part 1 – Requirements For Development, Validation and Sterilization Process for Medical Devices.

Sterilization Summary	
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	Gamma Radiation 25-40 kGy
Sterility Assurance Level	(SAL) – 10^{-6}
Pyrogen Tests	The device is non pyrogenic. Pyrogen testing is conducted on a lot-to-lot basis using the "Guideline for Validation of LAL Test as an End-Product Endotoxin Test for Medical Devices, (FDA 1978)."
Contract Sterilization	Sterigenics 344 Bonnie Circle. Corona, CA 92880

18. Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the HES-HydroSoft and MCS-HyperSoft coils when compared with the predicate devices K070656, HydroCoil Embolic System- HES-HC-HS (10) and K050954, MicroPlex Coil System and HydroCoil Embolic System.

The devices,

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

In summary, the HES-HydroSoft and MCS-HyperSoft coils described in this submission is, in our opinion, substantially equivalent to the predicate devices.

19. ISO/EC Certification and Compliance

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

Copy of the MicroVention ISO 13485 Certificate is provided in the Attachment 7.

20. List of Attachments

Attachment 1 ..... Product Labels, Instructions For Use

Attachment 2 ..... Product Drawing

Attachment 3 ..... QP 4.1, Design and Development Quality Procedure

Attachment 4 ..... QP 4.8, Risk Management Quality Procedure

Attachment 5 ..... Risk Management Files

- RA02001, HydroCoil Embolic System
- RA03001, MicroPlex Coil System

Attachment 6 ..... TR 06-052, HydroSoft Design Verification Report

TR09-095, HyperSoft Design Verification Report

Attachment 7 ..... MicroVention ISO Certificates

Attachment 1

Instructions for Use

HydroCoil Embolic System (HES)
HydroSoft

PD02165

Hydro*Coil*® 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 a helical coil that provides additional filling of the cerebrovascular aneurysm or lesion once the initial framework has been established by one or more complex framing coils. The MicroPlex® Coil System (MCS) complex coil is used to establish the initial framework. The MCS complex coil is packaged 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.

Coil Type	Stretch Resistant	Minimum Microcatheter I.D.		Reposition Time
		inches	mm	
HES HydroSoft™	●	0.015	0.38	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.

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.

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 complex 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 aneurysms, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential coil breakage and migration.

- 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.
- The long-term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- 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.

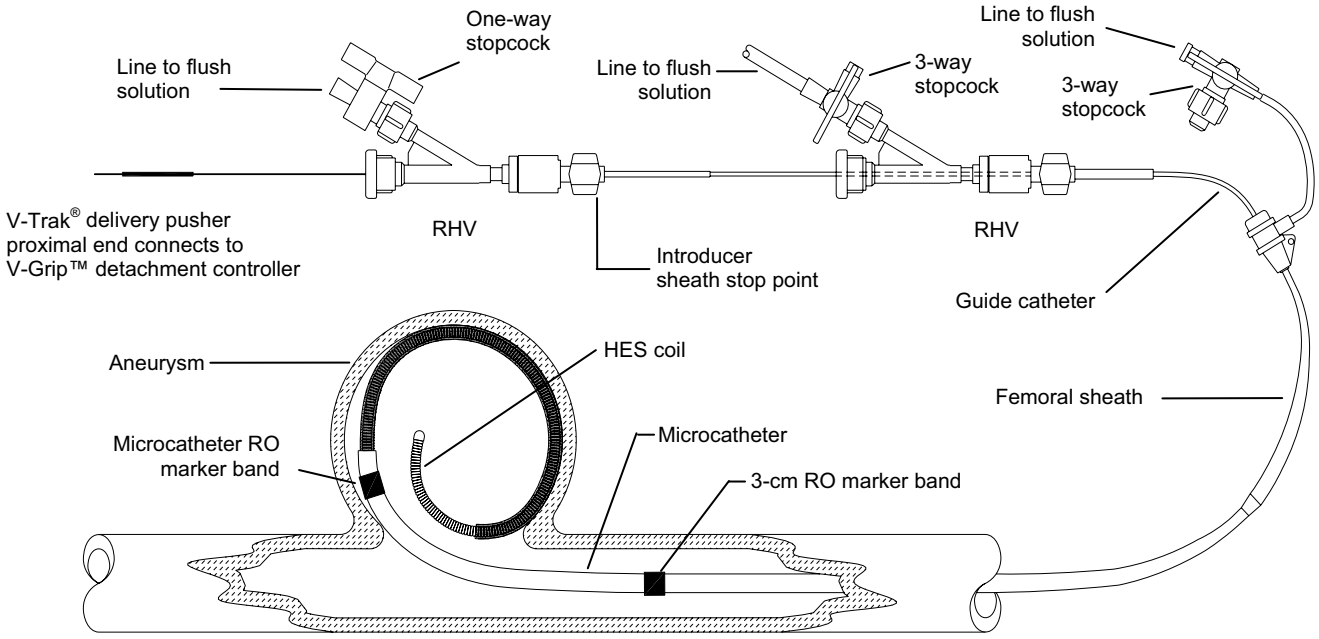


Diagram of HES Setup

PREPARATION FOR USE

1. Refer to the set-up diagram.
2. 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.
3. 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.
4. Open the stopcock and flush the microcatheter with sterile flush solution and then close the stopcock. 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.

CATHETERIZATION OF THE LESION

5. 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.
6. Select a microcatheter with the appropriate inner diameter. After the microcatheter has been positioned inside the lesion, remove the guidewire.

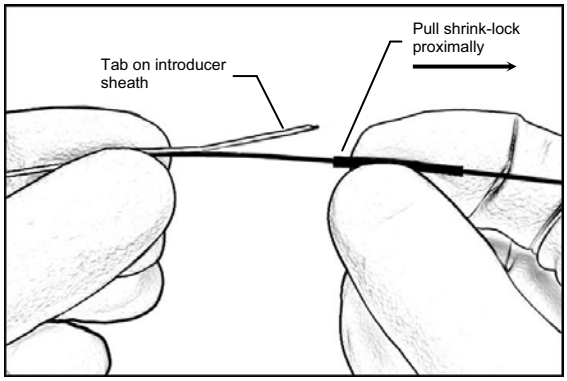
COIL SIZE SELECTION

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 MCS or HES complex 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. NOTE: The HES coils include an outer layer of a hydrophilic polymer. The primary coil diameter and the secondary coil diameter (dimension 'A' on the package label) will increase by approximately 0.5 mm following hydration.

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 MicroVention 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.

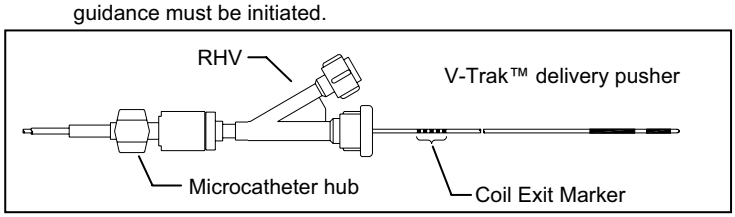


Pull Shrink Lock Proximally

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.

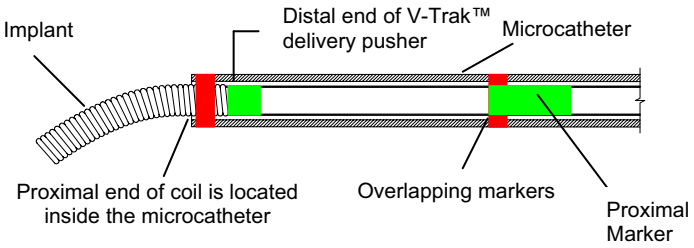
INTRODUCTION AND DEPLOYMENT OF THE HES

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.**



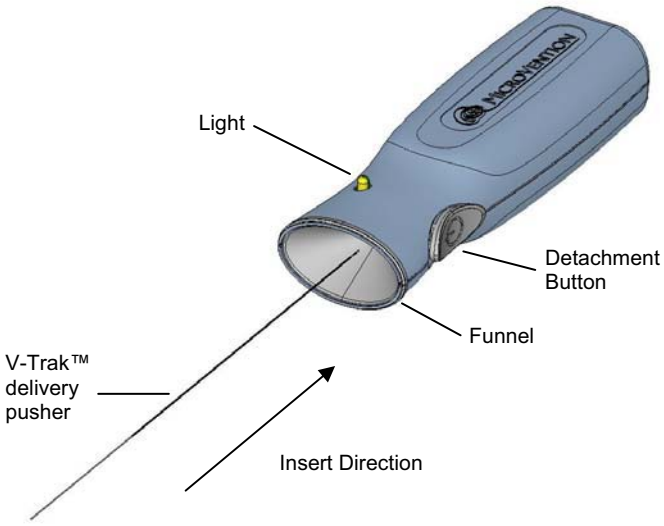
Position of Marker Bands for Detachment

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.

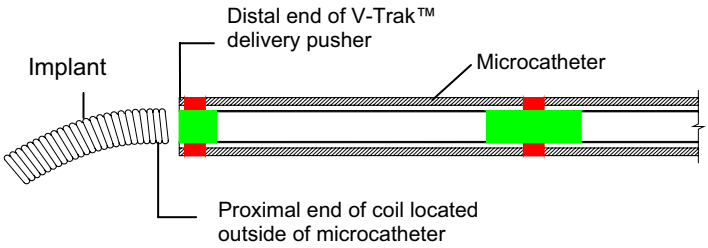
DETACHMENT OF THE HES COIL

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.

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 COMPATIBILITY

The HES implant materials have been determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International designation F2503-05. A patient can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

Optimization of MR imaging parameters is recommended.

MATERIALS

The HES does not contain latex or PVC materials.

SYMBOLS

The following symbols are used:

LOT	Lot Number
REF	Catalog Number
CONT	Content
STERILE R	Sterilized Using Irradiation
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use-by Date
	Date of Manufacture
	Attention, Consult Accompanying Documents
CE	CE Mark
	Type BF Applied Part
	Power ON and OFF
	Manufacturer
EC REP	Authorized European Representative

WARRANTY

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

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

This product is covered by one or more of the following US patents: 6,238,403, 6,299,619, 6,500,190, 6,602,261, 6,878,384, 7,014,645, and 7,201,762. Additional US and international patents are pending.

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

EC REP

Authorized European Representative:
MicroVention Europe
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France
Tel: +33 (1) 39 21 52 17
Fax: +33 (1) 39 21 16 01

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CE 0297

Instructions for Use

MicroPlex Coil System (MCS)
HyperSoft

PD03058

MicroPlex® Coil System (MCS)
(Endovascular Embolization Coil)
Instructions for Use

DEVICE DESCRIPTION

The MicroVention MicroPlex Coil System (MCS) consists of an implantable coil attached to a delivery system called a V-Trak® delivery pusher. The V-Trak® delivery pusher is powered by a V-Grip™ detachment controller designed specifically for the MCS. The V-Grip™ detachment controller is provided separately.

MCS complex coils establish the initial framework in the treatment of the cerebrovascular aneurysm or lesion. Once the initial framework has been established by one or more complex framing coils, additional MCS complex and helical coils provide filling of the cerebrovascular aneurysm or lesion.

The MCS is available in several coil types based on the coil primary diameter and configuration (complex and helical). Within each coil type is a broad range of coil secondary (loop) diameters and lengths to meet the needs of the physician. These coil types include 10 and 18 compatible systems and are delivered through the following wire-reinforced microcatheters with the specified minimum ID:

Coil Type	Minimum Microcatheter I.D.	
	inches	mm
MCS-10	0.015	0.38
MCS-18 All helical coils and complex coils 12 mm or smaller	0.0165	0.42
MCS-18 Complex coils 13 mm or larger	0.018	0.46

INDICATIONS FOR USE

The MicroPlex Coil System (MCS) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS 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 MCS 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.

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.

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
- Sterile saline
- Pressurized sterile saline drip
- 1 one-way stopcock

WARNINGS AND PRECAUTIONS

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

- The MCS is sterile and non-pyrogenic unless the unit package is opened or damaged.
- The MCS 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 MCS 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 MCS and microcatheter from the patient.
- High quality, digital subtraction fluoroscopic road mapping is **mandatory** to achieve correct placement of the MCS.
- Do not advance the V-Trak® delivery pusher with excessive force. Determine the cause of any unusual resistance, remove the MCS and check for damage.
- Advance and retract the MCS device slowly and smoothly. Remove the entire MCS if excessive friction is noted. If excessive friction is noted with a second MCS, check the microcatheter for damage or kinking.
- 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 MCS coils, the tortuous vascular pathways that lead to certain aneurysms and vessels, and the varying morphologies of intracranial aneurysms, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential coil breakage and migration.
- 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 MCS coils is usually required to achieve the desired occlusion of some aneurysms or lesions. The desired procedural endpoint is angiographic occlusion.
- The long-term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- Always ensure that at least <u>two</u> MicroVention V-Grip™ detachment controllers are available before starting a MCS procedure.
- The MCS 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 <u>NOT</u> place the V-Trak® delivery pusher on a bare metallic surface.
- Always handle the V-Trak® delivery pusher with surgical gloves.
- Do <u>NOT</u> use in conjunction with radio frequency (RF) devices.

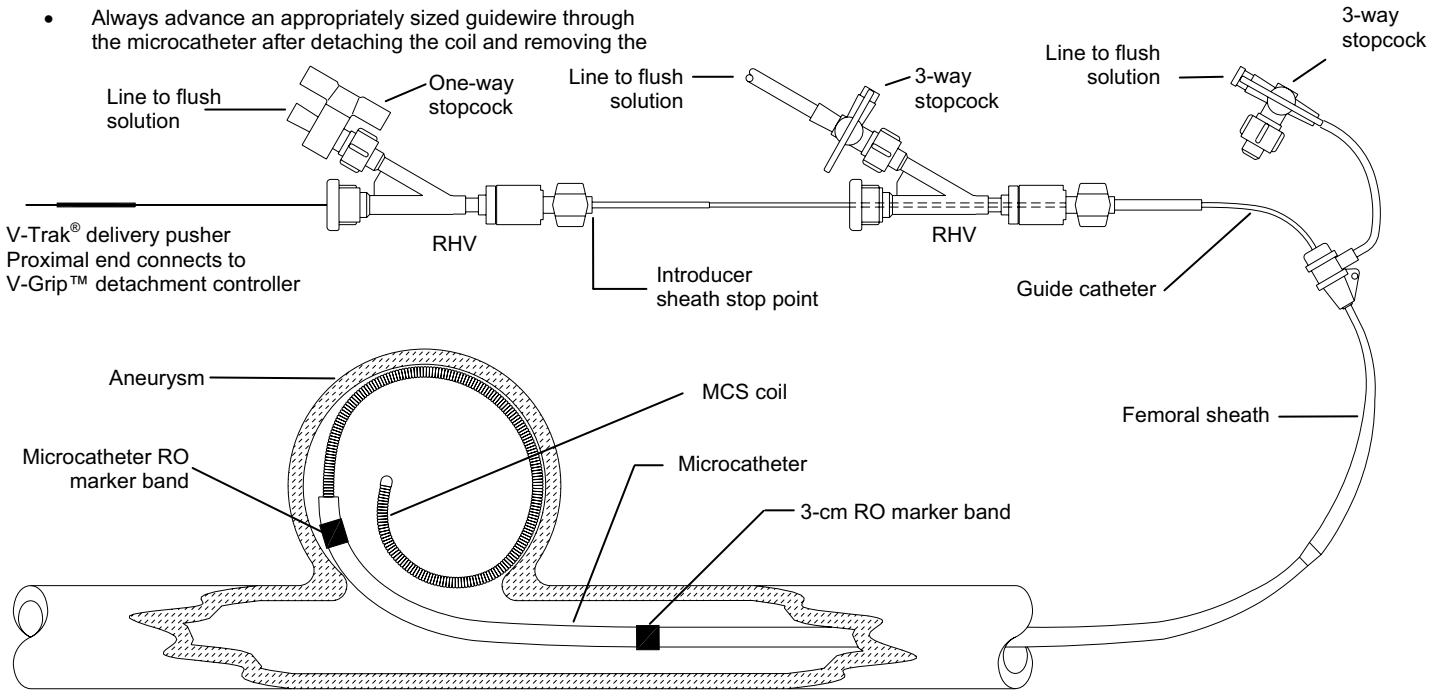


Diagram of MCS Setup

PREPARATION FOR USE

1. Refer to the set-up diagram.
2. 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.
3. 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.
4. Open the stopcock and flush the microcatheter with sterile flush solution and then close the stopcock. 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.

CATHETERIZATION OF THE LESION

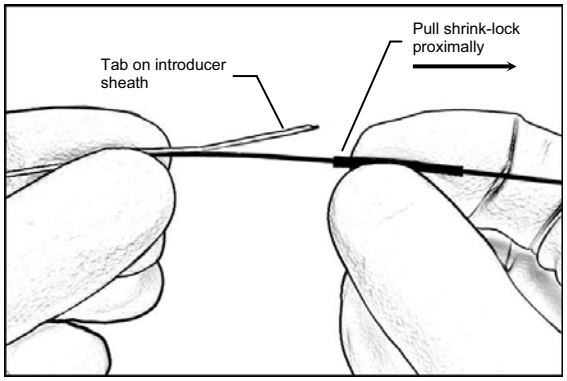
5. Using standard interventional procedures, access the vessel with a guide catheter. The guide catheter should have an inner diameter (ID) large enough to allow for contrast injection while the microcatheter is in place. This will allow for fluoroscopic road mapping during the procedure.
6. Select a microcatheter with the appropriate inner diameter. After the microcatheter has been positioned inside the lesion, remove the guidewire.

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.
10. Correct coil selection increases MCS effectiveness and patient safety. Occlusive efficiency is, in part, a function of compaction and overall coil mass. In order to choose the optimum MCS coil for any given lesion, examine the pre-treatment angiograms. The appropriate MCS coil size should be chosen based upon angiographic assessment of the diameter of the parent vessel, aneurysm dome and aneurysm neck. When accessing aneurysms, 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.

PREPARATION OF THE MCS 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 MicroVention 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. Remove the MCS from the packaging hoop by pulling the proximal end until the introducer exits the hoop.
15. Hold the device just distal to the shrink-lock and pull the shrink-lock proximally to expose the tab on introducer sheath.

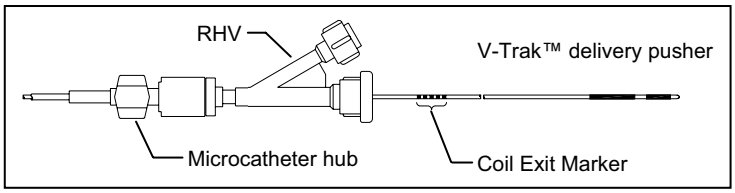


Pull Shrink-Lock Proximally

16. Slowly advance the MCS 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 system.**
17. While holding the introducer sheath vertically, gently retract the coil back into the introducer sheath about 1 to 2 cm.

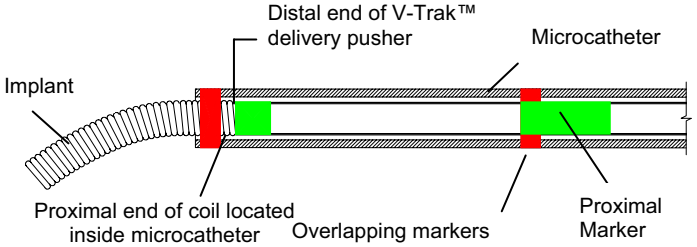
INTRODUCTION AND DEPLOYMENT OF THE MCS

18. Open the RHV on the microcatheter just enough to accept the introducer sheath of the MCS.
19. Insert the introducer sheath of the MCS 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.
21. Push the MCS 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.
22. Carefully advance the MCS 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

23. Under fluoroscopic guidance, slowly advance the MCS coil out the tip of the microcatheter. Continue to advance the MCS 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 MCS 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.
24. 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.**



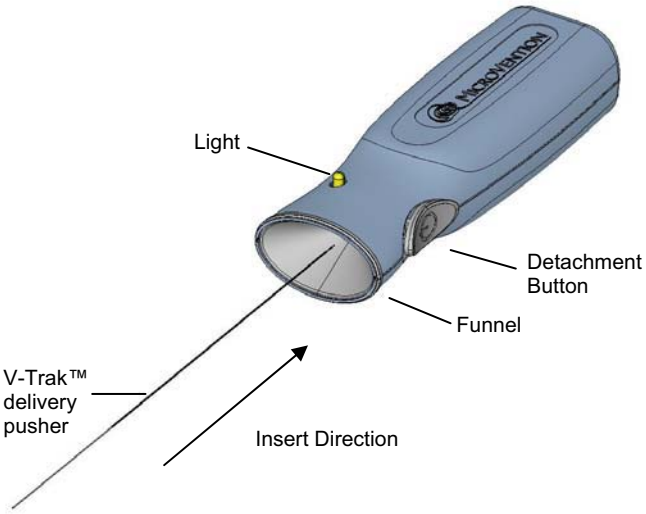
Position of Marker Bands for Detachment

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.

25. Tighten the RHV to prevent movement of the coil.
26. 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.

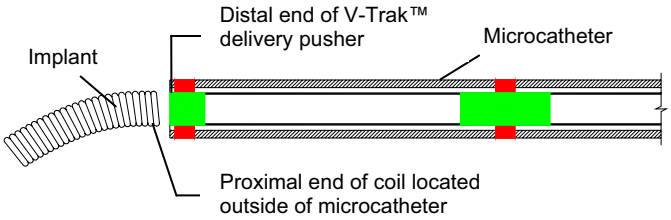
DETACHMENT OF THE MCS COIL

27. 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.
28. 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.
29. 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 before connecting the V-Grip™ detachment controller.
30. 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

31. 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.
32. Verify the coil position before pushing the detachment button.
33. Push the detachment button. When the button is pushed, an audible tone will sound and the light will flash green.
34. 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.
35. 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.
36. 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.
37. 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.**
38. After the coil is outside the microcatheter, pull the entire delivery system out of the microcatheter.
39. Verify the position of the coil angiographically through the guide catheter.



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

40. 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.

PACKAGING AND STORAGE

The MCS is placed inside a protective, plastic dispenser hoop and packaged in a pouch and unit carton. The MCS 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 MCS 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 MCS. 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 COMPATIBILITY

The MCS implant materials have been determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International designation F2503-05. A patient can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

Optimization of MR imaging parameters is recommended.

MATERIALS

The MCS does not contain latex or PVC materials.

SYMBOLS

The following symbols are used:

LOT	Lot Number
REF	Catalog Number
CONT	Content
STERILE R	Sterilized Using Irradiation
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Reuse
	Use-by Date
	Date of Manufacture
	Attention, Consult Accompanying Documents
	Type BF Applied Part
	Power ON and OFF
CE	CE Mark
	Manufacturer
EC REP	Authorized European Representative

WARRANTY

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

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

This product is covered by one or more of the following US patents: 6,605,101 and 7,029,486. Additional US and international patents are pending.

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

EC REP

Authorized European Representative:
MicroVention Europe
30 bis, rue de Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France
Tel: +33 (1) 39 21 52 17
Fax: +33 (1) 39 21 16 01

PD03058 Rev. F
Revised 2008-06

CE 0297

HydroSoft™ 10

HydroCoil® Embolic System

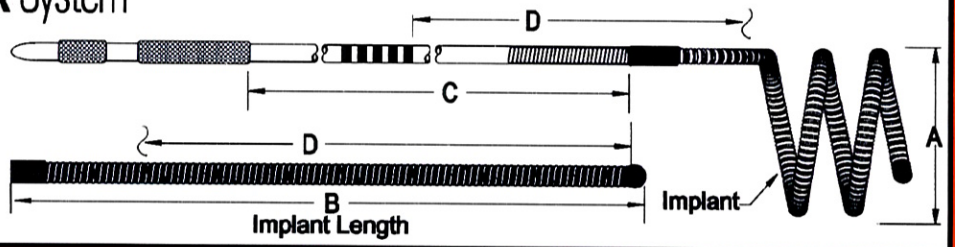
Endovascular Embolization Coil

Helical

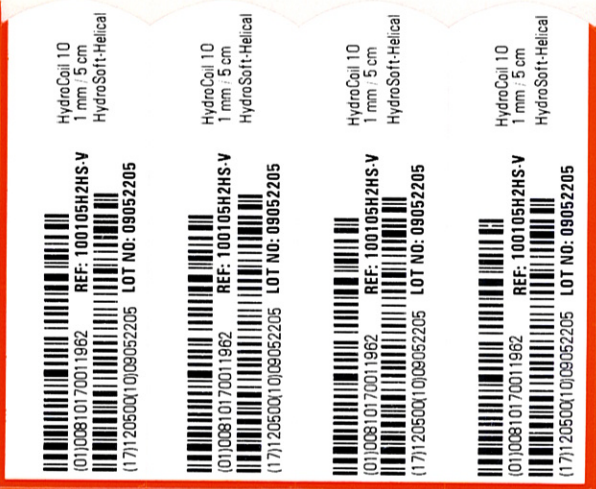
Stretch-Resistant

A **1 mm**	B **5 cm**	REF Catalog Number **100105H2HS-V**
C **175 cm**	D **148 cm**	LOT Lot Number **09052205**

V-Trak® System



ED2011-002



MICROVENTION® TERUMO

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

CE 0297 Made in U.S.A.

CONT 1 Contents

STERILE R Sterilized Using Irradiation.

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

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 **2009-05**

Use By **2012-05**

LB02043 Rev. B 2008-03

LB02044-0105

HydroSoft™ 10 HydroCoil® Embolic System

Helical

S R 1 mm / 5 cm

Use By 2012-05
REF 100105H2HS-V

V-Trak®

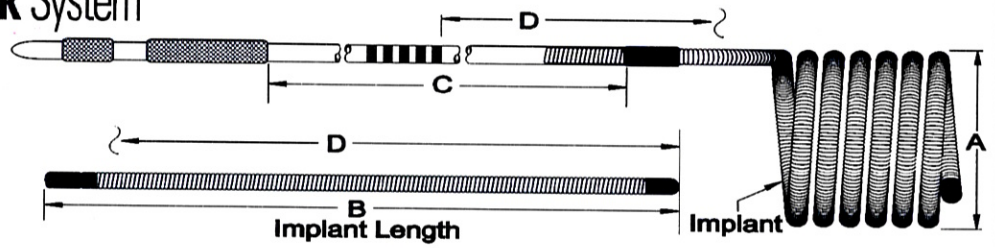
MICROPLEX® 10
PLATINUM coil system

Endovascular Embolization Coil

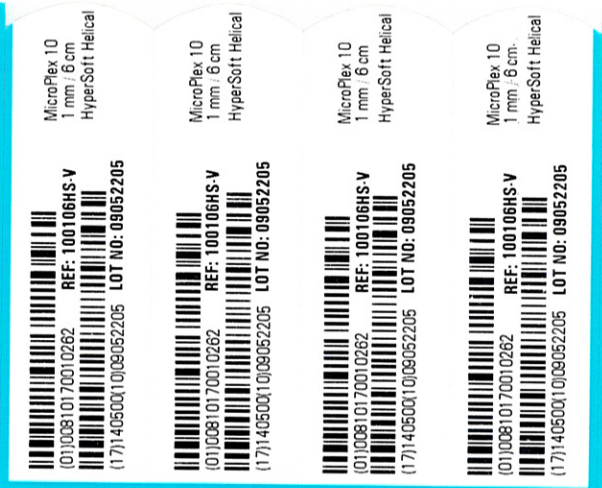
HYPERSOFT® finishing coil Helical
Stretch-Resistant

A 1 mm	B 6 cm	REF Catalog Number 100106HS-V
C 175 cm	D 148 cm	LOT Lot Number 09052205

V-Trak® System



ED2011-002



MICROVENTION® TERUMO

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

CE 0297
Made in U.S.A.

CONT 1 Contents

STERILE R
Sterilized Using Irradiation.

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

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 2009-05

Use By 2014-05

LB03120 Rev. D 2008-06

LB04117-0106

MICROPLEX 10 PLATINUM coil system

HYPERSOFT Helical finishing coil

S R 1 mm / 6 cm

Use By 2014-05
REF 100106HS-V

V-Trak

Attachment 2

Pages 79 through 90 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

Attachment 3

Pages 92 through 105 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

Attachment 4

Pages 107 through 135 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

Attachment 5

Pages 137 through 157 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

Attachment 6

Pages 159 through 169 redacted for the following reasons:
- -
(b)(4)-Trade Secret/Commercial Confidential Information-Process Information

Attachment 7

CERTIFICATE

DQS GmbH

Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies that the company

MicroVention, Inc.

75 Columbia, Ste.A
Aliso Viejo, CA 92656
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:

DIN EN ISO 13485 : 2003
November 2003 edition

This certificate is valid until	2013-11-20
Certificate Registration No.	411133 MP23
Frankfurt am Main	2008-11-21

Ass. iur. M. Drechsel

Dipl.-Ing. S. Heinloth

MANAGING DIRECTORS

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

DQS a member of IQNet THE INTERNATIONAL CERTIFICATION NETWORK

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten

ZLG-ZQ-987.99.07-46

EC-CERTIFICATE

DQS GmbH

Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certifies that the company

MicroVention, Inc.

75 Columbia, Ste.A
Aliso Viejo, CA 92656
United States of America

has implemented and maintains a

Quality Management System.

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

Annex II of Directive 93/42/EEC

with respect to the following medical devices:

as listed in the annex

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

CE 0297

This certificate is valid until	2011-10-29
Certificate Registration No.	411133 MR2
Frankfurt am Main	2008-07-22

Ass. iur. M. Drechsel

Dipl.-Ing. S. Heinloth

MANAGING DIRECTORS

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

EC code number of DQS as notified body: 0297

Annex to Certificate Registration No.: 411133 MR2
(Edition 2008-07-22)

MicroVention, Inc.

75 Columbia, Ste.A
Aliso Viejo, CA 92656
United States of America

Products:

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

This annex (Edition: 2009-03-16) is only valid in connection with the above-mentioned certificate.

cc: HFZ- 401 DMC
HFZ- 404 510(k) Staff
HFZ- 460 Division DONED
D.O.

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Drafted:
Edited:
Final:
Typed: Marisol Lendor,

IMAGE COPY

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
Z460	Tay	6/24						
460	Yuner	6/23						
Z-460	Alexander	9/29/09						

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

COVER SHEET MEMORANDUM

From: Reviewer Name Jeffrey Toy

Subject: 510(k) Number K091641

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.). SE

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*	/	X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
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)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21		X	X
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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

Regulation Number **Class*** **Product Code**

882.5950 II HCG

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

Additional Product Codes:

Review: for Q Hoang (Branch Chief) ANDB (Branch Code) 6/25/09 (Date)

Final Review: Kevin Alexander for Eydelman (Division Director) 6-29-09 (Date)

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

K091641

Date: **June 24, 2009**
Reviewer: **Jeffrey Toy, Ph.D.**
Division/Branch: **DOED/VEDB**
Device Name: **MicroVention HydroCoil Embolic System (HES) - HydroSoft Coils and MicroPlex Coil System (MCS) – HyperSoft Coils**
Classification: **Class II** Procode: **HCG**
CFR **882.5950** Name: **Neurvascular Embolization Device**
To: THE FILE **RE:** DOCUMENT NUMBER K091641

RECOMMENDATION: SUBSTANTIALLY EQUIVALENT

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 (delete/add items as necessary):

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.)

   K070656 HydroCoil Embolic System with the HES-HC-HS (10) [marketed under the HydroSoft name]
   K050954 MicroPlex Coil System and HydroCoil Embolic System

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).

   The subject's Indication For Use (IFU) is virtually identical to the two predicate IFUs. The subject and predicate IFUs are provided below.

   The HydroCoil Embolic System and MicroPlex Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and anteriorvenous fistulae. The HES/MCS 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. [K091641 Subject]

   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. [K070656 Predicate]

   The MicroPlex® Coil System (MCS) and HydroCoil® Embolic System (HES) are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS and HES 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 embolizations in the peripheral vasculature. [K050954 Predicate]

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**.

   This change was for

   DEVICE DESCRIPTION AND ENGINEERING – MicroVention submitted two configurations of coils in the 510k: the HydroCoil Embolic System (HES)-HydroSoft and MicroPlex Coil System (MCS)-HyperSoft. **For this special, MicroVention added the following additional coil sizes to both coils that are cleared: HES- HydroSoft 1mm diameter coil sizes (NEW) and MCS-HyperSoft 1mm diameter coil sizes (NEW).** Note: The HES-HC-HS (10) coils cleared under 510(k) K07656 were later marketed under the HES-HydroSoft name. The HES-HydroSoft coils consist of an implant coil made of bare platinum alloy (Platinum/Tungsten) with an inner hydrogel core. The MCS-HyperSoft coils are similar to the HES-HydroSoft coils with the exception of no inner hydrogel core. For both coil configurations, there is no change to the design technology and the principal of operation. The in vitro testing covered the physical, mechanical, and functional performance of the coils. These tests validated the performance characterization of these coils. The combined conclusion from these tests demonstrates that the in vitro behavior of these coils is well characterized within the design specifications. Joe Hutter reviewed the engineering and testing information.

   BIOCOMATIBILITY – MicroVention used the same material that is used in the existing configurations of the HESHydroSoft and MCS-Hypersoft coils (page 45-47 of 152).

   STERILITY AND PACKAGING – There is no change to the packaging and sterilization method. The coils are packaged in the same packaging configuration as the existing coils. The product is sterilized using the same gamma sterilization cycle (page 45 and 48 of 152).

   LABELING – There is no change to the intended use and Instructions for Use (page 31 of 152).

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

   MicroVention provided two tables (attached) comparing: 1) the cleared HES-HydroSoft (predicate) to the HES-HydroSoft line extension (subject) and 2) the cleared MCS-HyperSoft (predicate) to the MCS-HyperSoft line extension (subject). The parts of the table describing the change in the 510k special is reproduced below (page 35 and 36 or 152):

Device Model	Parameters	
	Secondary Coil Diameter	Restrained Length
Predicate HES-HydroSoft (K070656)	2-6 mm	1-8 cm

8

Subject HES HydroSoft	1 mm	1-5 cm
Predicate MCS-HyperSoft (K050954)	2-8 mm	1-10 cm
Subject MCS HyperSoft	1 mm	1-6 cm

All other parameters are identical. The labeling and intended use of the subject is identical to the predicate.

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.

Declaration of Conformity and Design Controls – Signed and dated statements on verification activities and manufacturing provided on page 25.

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

Indication For Use Enclosure – Completed form provided on page 17

510k Summary – A 510k Summary was provided on page 14

Truthful and Accurate Statement – Completed, signed and dated from provided on page 12

Form FDA 3674 – Completed, signed and dated form provided on page 19, 20 and 21.

Form FDA 3654 – Completed form provided on page 23 and 24.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Comments Concur (Reviewer's Signature) for Q Hoang (Date) 6/25/09

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	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:
See #2 above
2. Explain why there is or is not a new effect or safety or effectiveness issue:
See #3 and #4 above
3. Describe the new technological characteristics:
See #3 above
4. Explain how new characteristics could or could not affect safety or effectiveness:
Not applicable to this device change
5. Explain how descriptive characteristics are not precise enough:
Not applicable to this device change
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
Not applicable to this device change
7. Explain why existing scientific methods can not be used:
Not applicable to this device change
8. Explain what performance data is needed:
Not applicable to this device change
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Review Template Rev. 12/01/08

Sterile Devices in Premarket Notification [510(k)] Submissions

For:

- Sterile, Single Use Devices (SUD)
- Reusable Devices
- Non-Sterile SUDs, to be sterilized once by a Health Care Facility
- Reprocessed SUDs
- Devices subject to Aseptic Processing and Filtration Methods

See the Guidance:

- Updated 510(k) Sterility Review Guidance K90-1; August 30, 2002[1]
- Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, 1996.
- MDUFMA, Validation Data in 510(k)s for Reprocessed SUDs[2]
- See relevant guidance.

Sterilization Method	Additional Procedures for Non-traditional Sterilization Methods
Traditional	1. Refer to Infection Control Devices Branch (INCB) Chief for consideration. 2. INCB will advise ODE reviewing Division, and OC for appropriate action.
Non-traditional	Same as "1" and "2" above. In addition, INCB, the reviewing Division Director, ODE Deputy Director for Science and Regulatory Policy, and OC will determine the need for a Pre-Market Inspection
"Novel Non-traditional"	

For 510(k) devices proposed to be sterilized by Traditional and Non-traditional methods, FDA Reviewers should use the following review criteria to evaluate and document the sterilization information.

[1] *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA Document Issued on: August 30, 2002*
[2] *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single Use Devices*

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, Radiation):	Radiation	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	25-40 kGy	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);		
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.))	ISO 11137-1: 2006 Medical Devices – Sterilization of health care products radiation: Part 1 – Requirements for development, validation and sterilization process for medical devices	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	$1x10^{-6}$	
4. Is it labeled "Pyrogen Free"?	Yes	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Guideline for validation of LAL test as an end-product test for medical devices (FDA 1978)	
5. A description of the packaging (not including package integrity test data):	Pouch: MCS - polyester/Tyvek; HES – polyester. Pouch in carton box	

[1] *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA Document Issued on: August 30, 2002*

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

To: THE FILE **RE:** DOCUMENT NUMBER K 091641

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 (delete/add items as necessary):

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 following 2 devices will be modified:
   K070656 Hydrocoil Embolic System with the HES HC-HS (10)
   K050954 Microplex Coil System and Hydrocoil Embolic System

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).

The proposed indications are:

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

Analysis – The indications are identical to those cleared in K070656 and K050954. Microvention stated that intended us was the same on p 15. Labeling was provided and ino changes in intended use were indicated.

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.**

This change was for decreasing the secondary dia of the coils and changing the length of the coils slightly. The firm has established the following definitions for their design.

Primary dia- The Pt alloy wire is coiled into helical primary structure. The properties of the wire itself did not change, the dia of the wire and its tensile strength are the same as the predicates, the primary dia also did not change from the predicate devices.

Secondary dia- After the primary coil is formed, the wire is wrapped into a secondary helical coil. In the proposed change, this will be a dia of 1 mm. In the predicate devices, the secondary dia was in the range 2-6 mm (HES) and 2-8 mm (MCS). The new length will be 1-5 cm, the predicate coils had lengths from 1-8 cm.

There were no changes to the deployment system, couplers, elastomers, or internal filaments (hydrogels, HES only has an internal hydrogel filament).

Analysis- The fundamental function to occlude aneurysms or blood vessels has not changed. Its standard practice to introduce small coils into vasculature after larger framing or filling coils are deployed.

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 p 36-37.

Analysis – The design of the device has changed only slightly and should not affect safety or effectiveness.

Conclusion- Adequate comparison information was provided to demonstrate SE.

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

A failure modes effect analysis was completed.

Analysis- The firm has correctly identified the major risks with this design change: deployment difficulties, detachment and positioning, tensile strength of the coupler, advancement and retraction force, spring constant, coupler to coil weld strength, hydrogel expansion (HES only).

   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

Performance testing was completed as documented in Section 14.

   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

      Signed statement provided on p 25

      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.

      Signed statement provided on p 25.

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

A signed truthful and accuracy statement was provide on p 12.

B

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

(Reviewer's Signature)

JUNE 25, 2004
(Date)

Comments

This is Joe Hutter's consult Memo

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

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

Note: See http://eroom.fda.gov/eRoomReg/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:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: