MicroVention TERUMO

K132317

510(K) SUMMARY

Trade Name: MicroPlex Coil System (MCS), VFC

Generic Name: Neurovascular Embolization Device

Classification: Class II, 21 CFR 882.5950

Date Submitted August 22, 2013

SEP 2 0 2013

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

Contact: Laraine Pangelina

Predicate Device: MicroPlex Coil System (MCS) (K111451)

Indications for Use: The MicroPlex Coil System 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.

Device Description: The MCS VFC consists of an implantable coil made of bare platinum alloy. The MCS VFC implantable coils has a 3D shape in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Bench Test Summary:

Test	Results
Visual/Dimensional Inspection Perform visual inspection and measurments using device drawing	PASS, acceptance criteria met
Simulate Use Introduction, Tracking, Deployment, Compartmentalizing, Frame Movement, Microcatheter movement, Detachment, Overall Performance	PASS, acceptance criteria met
Detachment Test Confirm successful detachment according using V-Grip Detachment Controller during simulated use testing	PASS, acceptance criteria met
Coil-to-Coupler Weld Test Test the tensile strength of the coil/coupler weld	PASS, acceptance criteria met
Spring Constant Measure the spring constant force of the coil	PASS, acceptance criteria met
CONCLUSION: The results of the bench testing demonstrate that the subject device is safe and effective when used according to the instructions for use and performs equivalent to the predicate device. The testing was used in support of the risk analysis documentation for the subject device.	

Predicate / Subject Technological Comparison:

Feature	Predicate Devices	Subject Device
Coil shape	3D	Same
Coil OD (mm)	3 - 15	1
Restrained coil length (cm)	6 - 45	3
Main coil wire material	Platinum/Tungsten (92/8%) alloy	Same
Coupler Material	Platinum (90%)/ iridium (10%)	Same
Adhesive Material	DYMAX 1128-AM-VT UV Adhesive	Same
Stretch resistance filar material	Polyolefin Elastomer or PET	Same
Implant-to-pusher material	Polyolefin elastomer	Same
Delivery method	V-Trak delivery pusher	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, shipping carton	Same

Summary of Substantial Equivalence:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 20, 2013

MicroVention, Inc.
Ms. Laraine Pangelina
Sr. Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K132317
Trade/Device Name: MicroPlex Coil System (MCS), VFC
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG
Dated: August 22, 2013
Received: August 23, 2013

Dear Ms. Pangelina:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132317

Device Name: MicroPlex Coil System (MCS), VFC

Indications For Use: The MicroPlex Coil System 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 embolization 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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _K132317_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K132317/S001

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Jeff Toy, 9/18/13
Branch Chief Sign-Off	Quynh Hoang DNPMD/NNDB 9/20/13
Division Sign-Off	Joyce M. Whang -S 2013.09.20 16:55:23 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

Indications for Use

510(k) Number (if known): K132317

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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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K132317

4

MicroVention
TERUMO

SECTION/ECOPY PDF FILE# 004

COVER LETTER

K132317

FDA CDRH DMC
JUL 25 2013
Received

July 19, 2013

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

RE: Special 510(k), MicroPlex Coil System (MCS) Line Extension

Dear Sir/Madam:

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

The subject of this Special 510(k) is a line extension to the MicroPlex Coil System (MCS). One additional coil size will be added to the VFC (formerly Vector) type of the MCS products. The cleared VFC is available with implantable coils ranging in size from 3 – 15mm (nominal loop diameter) and 6 – 60cm (restrained length). The additional coil dimension is 1mm X 3cm. The purpose for the line extension is based on physician request and the availability of smaller competitive coils.

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

eCopy Statement: We are submitting two paper copies of this 510(k) and also including a CD containing an eCopy which is an exact duplicate of the paper copy. The hard copy and CD each contain the following:

001_Table of Contents
002_MDUFMA User Fee Cover Sheet Form FDA 3601
003_CDRH Premarket Review Submission Cover Sheet
004_510(k) Cover Letter (this letter)
005_Premarket Notification Truthful & Accurate Statement
006_510(k) Summary
007_Indications for Use Statement
008_Declaration of Conformity with Design Controls
009_Form FDA 3654
010_Form FDA3674
011_Executive Summary
012_General Information
013_Device Description and Engineering Drawing
014_Substantial Equivalence Discussion
015_Risk Analysis
016_Labeling
017_Product performance Bench Testing
018_Packaging, Sterilization and Shelf Life
019_Biocompatibility
020_Quality System Compliance

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

Sincerely,
Laraine Pangelina
Laraine Pangelina
Sr. Regulatory Affairs Project Manager

SS

SECTION/ECOPY PDF FILE# 001

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SECTION/ECOPY PDF FILE# 002

Medical Device User Fee Cover Sheet

Site: null

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Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade
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
1311 Valencia Avenue
Tustin
CA 92780
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4) Trade

2. CONTACT NAME
Vin Cutarelli
2.1 E-MAIL ADDRESS
vin.cutarelli@microvention.com
2.2 TELEPHONE NUMBER (include Area code)
714-247-8181
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
714-247-8014

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

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)
[ ] 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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
21-Jun-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

https://userfees.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?vcname=Vin%20Cu... 6/21/2013

MicroVention TERUMO

SECTION/ECOPY PDF FILE# 003

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
July 19, 2013	(b)(4) Trade Secret [redacted]	

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 MicroVention, Inc	Establishment Registration Number *(if known)* 2032493		
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (714) 247-8150		
Street Address 1311 Valencia Avenue	FAX Number *(including area code)* (714) 247-8014		
City Tustin	State / Province CA	ZIP/Postal Code 92780	Country USA
Contact Name Laraine Pangelina			
Contact Title Sr. Regulatory Affairs Project Manager	Contact E-mail Address laraine.pangelina@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)*:

MCS Line Extension, VFC family

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**

- [x] 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	K1111451	1	MicroPlex Coil System (MCS)	1	MicroVention, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Neurovascular Embolization Device

	Trade or Proprietary or Model Name for This Device		**Model Number(s)**
1	MicroPlex Coil System (MCS), VFC	1	VFC010303-V

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

1	2	3	4	5	6

Data Included in Submission

- [x] 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

- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

Intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

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

(b)(4) Trade Secret Process

[redacted]

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration 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.					
	Standards No.	**Standards Organization**	**Standards Title**	**Version**	**Date**
1					
2					
3					
Please include any additional standards to be cited on a separate page.					

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

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

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MicroVention
TERUMO

SECTION/ECOPY PDF FILE# 004

COVER LETTER

July 19, 2013

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

RE: Special 510(k), MicroPlex Coil System (MCS) Line Extension

Dear Sir/Madam:

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

The subject of this Special 510(k) is a line extension to the MicroPlex Coil System (MCS). One additional coil size will be added to the VFC (formerly Vector) type of the MCS products. The cleared VFC is available with implantable coils ranging in size from 3 – 15mm (nominal loop diameter) and 6 – 60cm (restrained length). The additional coil dimension is 1mm X 3cm. The purpose for the line extension is based on physician request and the availability of smaller competitive coils.

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

eCopy Statement: We are submitting two paper copies of this 510(k) and also including a CD containing an eCopy which is an exact duplicate of the paper copy. The hard copy and CD each contain the following:

001_Table of Contents
002_MDUFMA User Fee Cover Sheet Form FDA 3601
003_CDRH Premarket Review Submission Cover Sheet
004_510(k) Cover Letter (this letter)
005_Premarket Notification Truthful & Accurate Statement
006_510(k) Summary
007_Indications for Use Statement
008_Declaration of Conformity with Design Controls
009_Form FDA 3654
010_Form FDA3674
011_Executive Summary
012_General Information
013_Device Description and Engineering Drawing
014_Substantial Equivalence Discussion
015_Risk Analysis
016_Labeling
017_Product performance Bench Testing
018_Packaging, Sterilization and Shelf Life
019_Biocompatibility
020_Quality System Compliance

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

Sincerely,
Laraine Pangelina
Laraine Pangelina
Sr. Regulatory Affairs Project Manager

SECTION/ECOPY PDF FILE# 005

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

As required by 21 CFR §807.87(k)

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

Signature

Laraine Pangelina, Sr. Regulatory Affairs Project Manager
Printed Name

7-19-13
Date

Premarket Notification Number (if known)

SECTION/ECOPY PDF FILE# 006

510(K) SUMMARY

Trade Name: MicroPlex Coil System (MCS), VFC

Generic Name: Neurovascular Embolization Device

Classification: Class II, 21 CFR 882.5950

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

Contact: Laraine Pangelina

Predicate Device: MicroPlex Coil System (MCS)

Indications for Use: The MicroPlex Coil System 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.

Device Description: The MCS VFC consists of an implantable coil made of bare platinum alloy. The MCS VFC implantable coils has a 3D shape in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Bench Test Summary:

Test	Result
Visual/Dimensional Inspection	Met established criteria
Simulated Use	Met established criteria
Detachment Test	Met established criteria
Coil to Coupler Weld Tensile	Met established criteria
Spring Constant	Met established criteria

Predicate / Subject Technological Comparison:

Feature	Predicate Devices	Subject Device
Coil shape	3D	Same
Coil OD (mm)	3 - 15	1
Restrained coil length (cm)	6 - 45	3
Main coil wire material	Platinum/Tungsten (92/8%) alloy	Same
Coupler Material	Platinum (90%)/ iridium (10%)	Same
Adhesive Material	DYMAX 1128-AM-VT UV Adhesive	Same
Stretch resistance filar material	Polyolefin Elastomer or PET	Same
Implant-to-pusher material	Polyolefin elastomer	Same
Delivery method	V-Trak delivery pusher	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, shipping carton	Same

Summary of Substantial Equivalence:

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

SECTION/ECOPY PDF FILE# 007

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: MicroPlex Coil System (MCS)

Indications for Use: The MicroPlex Coil System 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.

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

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

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION/ECOPY PDF FILE# 008

Declaration of Conformity with Design Controls

MicroPlex Coil System (MCS), VFC
Line Extension

I certify, to the best of my knowledge that:

- As required by the risk analysis, all design verification and design validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and

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

7-19-13

Laraine Pangelina
Sr. Regulatory Affairs Project Manager
MicroVention, Inc

Date

SECTION/ECOPY PDF FILE# 009

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

FORM FDA 3654 (9/07) Page 1 PSC Graphics (301) 443-1090 EF

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

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FORM FDA 3654 (9/07) Page 2

SECTION/ECOPY PDF FILE# 010

Form FDA 3674

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Laraine Pangelina

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

3. ADDRESS *(Number, Street, State, and ZIP Code)*
MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 714-247-8150
(Fax) 714-247-8014

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) **FOR DEVICES:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) *(Attach extra pages as necessary)*
MicroPlex Coils System (MCS), Cosmos 18

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

The undersigned declares, to the best of he/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Laraine Pangelina
(Title) Regulatory Affairs Project Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
MicroVention, Inc
1311 Valencia Avenue
Tustin, CA 92780

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 714-247-8150
(Fax) 714-247-8914

15. DATE OF CERTIFICATION
7-19-13

Form FDA 3674 (11/08) (FRONT)

SECTION/ECOPY PDF FILE# 011

EXECUTIVE SUMMARY

The MCS VFC device consists of an implantable coil made of bare platinum alloy (Platinum/Tungsten) designed in a 3D shape in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher via a polymer filament. The proximal end of the delivery pusher is inserted into a hand-held, battery-powered V-Grip Detachment Controller (sold separately). The implant detaches upon activation of the V-Grip.

The subject of this Special 510(k) is a line extension to the cleared MCS VFC products (K111451). The line extension is for 3mm OD x 3cm long (unrestrained length) implantable coil. This is the initial submission to FDA for this MCS VFC line extension, there is no prior submission.

Table 1 below lists the currently cleared MCS VFC devices and the device that is the subject of this submission.

Table 1 MCS VFC Models, Cleared and Line Extension

Model Number	Coil OD (nominal loop diameter)r	Unrestrained Coil Length
Cleared (K111451)		
VFC030606-V	3mm	6cm
VFC030610-V	3mm	10cm
VFC030615-V	3mm	15cm
VFC061020-V	6mm	20cm
VFC061030-V	6mm	30cm
VFC101530-V	10mm	30cm
VFC101540-V	10mm	40cm
VFC152040-V	15mm	40cm
VFC152060-V	15mm	60cm
Line Extension		
VFC010303-V	1mm	3cm

The VFC in the additional size is the same as the cleared predicate devices. There are no changes to material, intended use, principal of operation, or sterilization method. In vitro testing was performed to assess the physical, mechanical, and functional performance of the VFC in the additional size. Applicable testing is detailed in Sections 017, 018 and 019 of this submission.

SECTION/ECOPY PDF FILE# 012

GENERAL INFORMATION

12.1 PREDICATE DEVICE INFORMATION

MCS VFC (K111451)

12.2 DEVICE CLASSIFICATION INFORMATION

Device Trade Name:	MicroPlex Coil System (MCS), VFC
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

12.3 MANUFACTURER'S NAME, ADDRESS AND REGISTRATION

MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780
Facility Registration: #2032493

Contact
Laraine Pangelina
Sr. Regulatory Affairs Project Manager
Phone: 714-247-8150
Fax: 714-247-8014

12.4 STERILIZATION FACILITY'S NAME, ADDRESS AND REGISTRATION

Synergy Health (formerly Beam One)
9020 Activity Road, Suite D
San Diego, CA 92126

12.5 INTENDED 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.

SECTION/ECOPY PDF FILE# 013

DEVICE DESCRIPTION AND ENGINEERING DRAWING

The VFC MCS consists of an implantable coil made of bare platinum alloy (Platinum/Tungsten) designed in a 3D shape in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher via a polymer filament. The proximal end of the delivery pusher is inserted into a hand-held, battery-powered V-Grip Detachment Controller (sold separately). The implant detaches upon activation of the V-Grip.

The subject of this Special 510(k) is a line extension to the cleared MCS VFC products (K111451). The line extension is for 3mm OD x 3cm long (unrestrained length) implantable coil.

Figure 1 below is a representative photo of a VFC coil implant:

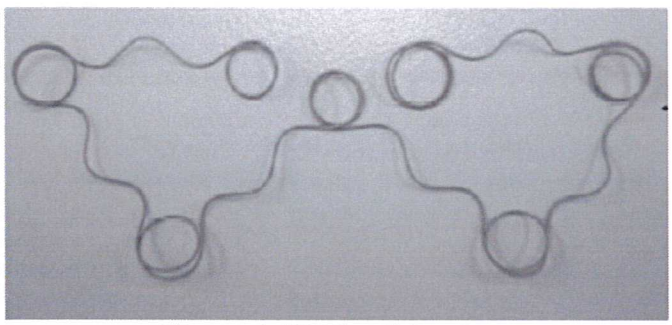

Figure 1 VFC coil implant

Figure 2 below illustrates the V-Trak delivery pusher.

Figure 2 MCS Coil with V-Trak Delivery Pusher

Figure 3 below illustrates the V-Grip Detachment Controller (sold separately)

Figure 3 V-Grip Detachment Controller

The VFC MCS is designed such that each size is able to treat a range of aneurysm spaces or other vascular spaces. VFC's ability to treat a range of spaces is a function of its loop and partial loop sections. For example, models with a nominal loop diameter of 3mm are designed to be placed in vascular spaces of 3mm to 6mm. When treating a 3mm space, the 3mm nominal loop diameter is sized appropriately to fit the 3mm space and the partial loop section conforms to the 3mm space. When treating a 6mm space, the 3mm loop together with the unrestrained partial loop section allows the coil to conform and remain inside the space. This design and performance attribute is true for all sizes.

Table 2 below lists the currently cleared MCS VFC devices and the device that is the subject of this submission.

Table 2 VFC Models

Model Number	Coil OD (nominal loop diameter)r	Unrestrained Coil Length	Treatable Space[1]
Cleared (K111451)			
VFC030606-V	3mm	6cm	3mm – 6mm
VFC030610-V	3mm	10cm	3mm – 6mm
VFC030615-V	3mm	15cm	3mm – 6mm
VFC061020-V	6mm	20cm	6mm – 10mm
VFC061030-V	6mm	30cm	6mm – 10mm
VFC101530-V	10mm	30cm	10mm – 15mm
VFC101540-V	10mm	40cm	10mm – 15mm
VFC152040-V	15mm	40cm	15mm – 20mm
VFC152060-V	15mm	60cm	15mm – 20mm
Line Extension			
VFC010303-V	1mm	3cm	1mm – 3mm

[1]**Note**: The VFC is a filling coil. The term "treatable space" refers to the amount of space that is remaining in a treatable location after framing and/or subsequent coils have been placed.

With the exception of the OD and length of the implant coil, the additional VFC model is essentially the same as the cleared predicate devices. There are no changes to material, intended use, principal of operation, or sterilization method. . Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. In vitro testing was performed to assess the physical, mechanical, and functional performance of the subject device. The test protocols and acceptance criteria for the subject devices were identical to those of the predicate devices. The subject devices met the same acceptance criteria as the predicate devices

An engineering drawing is provided in the following pages.

(b)(4) Trade Secret Process - Engineering Drawing

SECTION/ECOPY PDF FILE# 014

SUBSTANTIAL EQUIVALENCE DISCUSSION

COMPARISON WITH CLEARED DEVICE

Table 3 below compares the technological characteristics of the VFC additional size with the cleared predicate devices.

Table 3 Substantial Equivalence Comparison Chart

Feature	Predicate Devices	Subject Device
Coil shape	3D	Same
Coil OD (mm)	3 - 15	1
Restrained coil length (cm)	6 - 45	3
Main coil wire material	Platinum/Tungsten (92/8%) alloy	Same
Coupler Material	Platinum (90%)/ iridium (10%)	Same
Adhesive Material	DYMAX 1128-AM-VT UV Adhesive	Same
Stretch resistance filar material	Polyolefin Elastomer or PET	Same
Implant-to-pusher material	Polyolefin elastomer	Same
Delivery method	V-Trak delivery pusher	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, shipping carton	Same

SUBSTANTIAL EQUIVALENCE SUMMARY

With the exception of the OD and length of the implant coil, the additional VFC model is essentially the same as the cleared predicate devices. There are no changes to material, intended use, principal of operation, or sterilization method. . Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. In vitro testing was performed to assess the physical, mechanical, and functional performance of the subject device. The test protocols and acceptance criteria for the subject devices were identical to those of the predicate devices. The subject devices met the same acceptance criteria as the predicate devices. The results of the testing demonstrated that the VFC in the additional size is substantially equivalent to the predicate device.

SECTION/ECOPY PDF FILE# 015

RISK ANALYSIS

The MCS VFC products are designed, developed and tested in accordance with the MicroVention Design and Development procedure and with the MicroVention internal quality system procedure for risk management. Possible hazards and associated risk related to the device modification and clinical usage of the device were identified, examined and found to be acceptable after the implementation of the mitigation measures such as physician training program, labeling warnings and instructions for use.

The following Risk Management documentation is provided in the following pages.

- QP 4.1, Quality Procedure Design and Development Process
- QP 4.8, Quality Assurance Risk Management Procedure
- RA030001, MCS Risk Management File

  Note: RA030001is updated specific to the subject device. It includes an analysis of the impact of the specific modifications to the predicate device, the results of this analysis, and an analysis of what V&V testing is needed to address the identified risks of the device modifications.

(b)(4) Trade Secret Process - Risk Analysis

(b)(4) Trade Secret Process - Risk Analysis

(b)(4) Trade Secret Process - Risk Analysis

(b)(4) Trade Secret Process - Risk Analysis

(b)(4) Trade Secret Process - Risk Analysis

(b)(4) Trade Secret Process - Risk Analysis

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LABELING

The packaging label configuration and IFU for the VFC in the additional size is the same as the predicate devices. **For reference, a copy of the IFU is provided on the following pages**.

MicroVention® TERUMO

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:

Table 1

Coil Type	Minimum Microcatheter I.D.	
	inches	mm
MCS-18 Complex coils (except Cosmos), 13 mm or larger	0.0180	0.46
All other MicroPlex Coil System models	0.0165	0.42

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 compat ble 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 poss bly 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 poss ble 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 two 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 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.

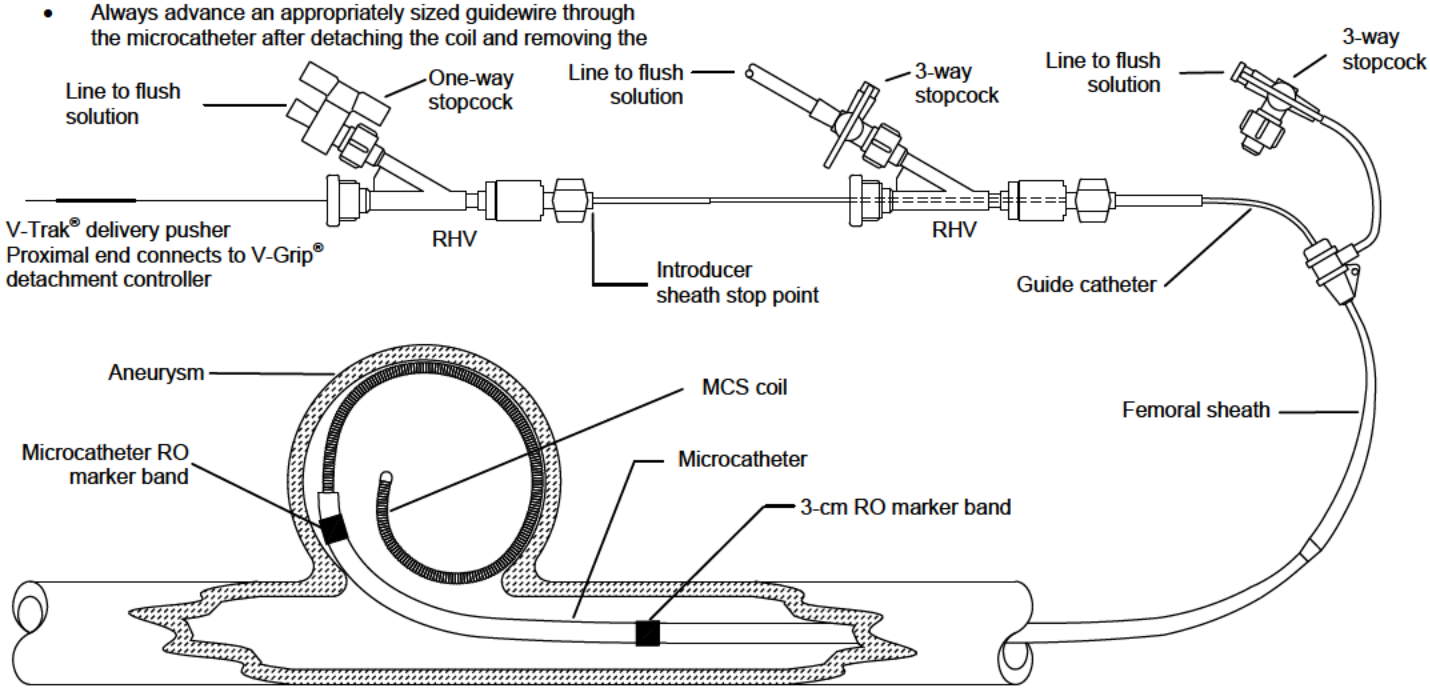


Diagram of MCS Setup

CATHETERIZATION OF THE LESION

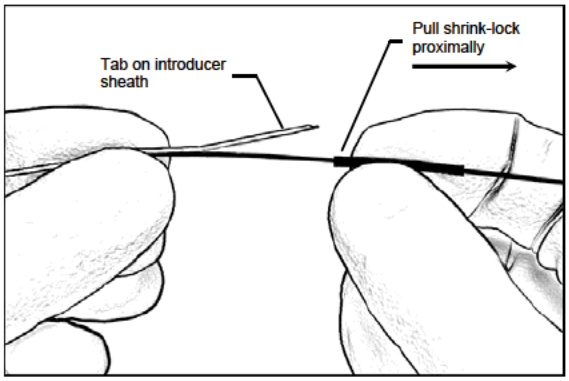
1. Refer to the set-up diagram.
2. Using standard interventional procedures, access the vessel with a guide catheter. The guide catheter should have an inner diameter (ID) large enough to allow for contrast injection while the microcatheter is in place. This will allow for fluoroscopic road mapping during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

COIL SIZE SELECTION

7. Perform fluoroscopic road mapping.
8. Measure and estimate the size of the lesion to be treated.
9. Select the appropriately sized coils.
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. Pull the white pull-tab from the side of the detachment controller. Discard the pull-tab and place the detachment controller in 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.

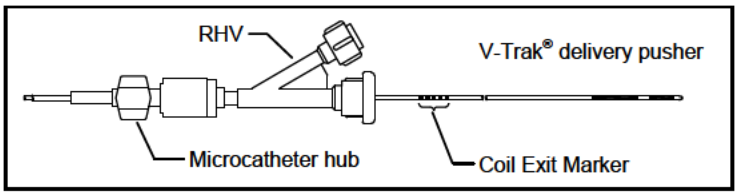


Pull Shrink-Lock Proximally

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.

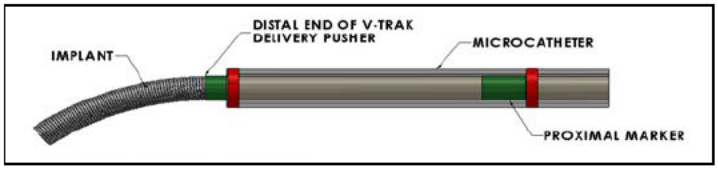
INTRODUCTION AND DEPLOYMENT OF THE MCS

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. Flush the introducer until it is completely purged of air and saline flush exits the proximal end.
20. 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.**
21. 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.
22. 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.
23. 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

24. 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.
25. Advance the coil into the desired site until the radiopaque proximal marker on the delivery system is aligned with the proximal marker on the microcatheter as shown.

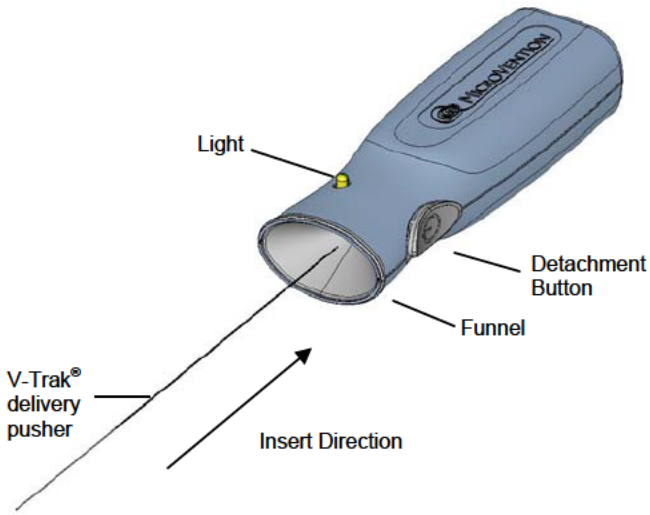


26. Tighten the RHV to prevent movement of the coil.
27. Verify repeatedly that the distal shaft of the V-Trak® delivery pusher is not under stress before coil detachment. Axial compression or tension could cause the tip of the microcatheter to move during coil delivery. Catheter tip movement could cause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

DETACHMENT OF THE MCS COIL

28. The V-Grip® detachment controller is pre-loaded with battery power 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.
29. 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.
30. 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.
31. 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

32. 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.
33. Verify the coil position before pushing the detachment button.
34. Push the detachment button. When the button is pushed, an audible tone will sound and the light will flash green.
35. 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.
36. 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.
37. 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.
38. After detachment has been confirmed, slowly retract and remove the delivery pusher. **Advancing the V-Trak® delivery pusher once the coil has been detached involves risk of aneurysm or vessel rupture. Do NOT advance the delivery pusher once the coil has been detached.**
39. Verify the position of the coil angiographically through the guide catheter.
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 ± 1 VDC
- Cleaning, preventative inspection, and maintenance: The V-Grip® detachment controller is a single use device, preloaded with battery power, 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 controllers. 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.

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.

SHELF LIFE

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

MR INFORMATION

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

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

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

MRI-Related Heating

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

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

Image Artifact Information

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

Pulse Sequence: *Plane Orientation:*	*T1-SE* *Parallel*	*T1-SE* *Perpendicular*	*GRE* *Parallel*	*GRE* *Perpendicular*
Signal Void Size:	*394 mm^2*	*73 mm^2*	*635 mm^2*	*220 mm^2*

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

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 Mark

Manufacturer

EC REP — Authorized European Representative

MR Conditional

Non-pyrogenic

Upper limit of temperature

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.

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Revised 2011-08

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SECTION/ECOPY PDF FILE# 017

PRODUCT PERFORMANCE BENCH TESTING

The VFC in the additional size is the same as the cleared predicate devices. There are no changes to material, intended use, principal of operation, or sterilization method. The same in vitro testing that was performed to assess the physical, mechanical, and functional performance of the predicate devices was performed with the VFC in the additional size.

Table 4 below summarizes the test results:

Table 4 Bench Testing Performed with VFC Line Extension

Test	Confidence/Reliability)	Samples	Acceptance Criteria	Results
Visual Inspection	90%/90%	22	• Max O.D. on implant 0.0145" • Must have soft UV distal tip • Stretch resistant member connected at both ends • Implant length • No obvious kinks or damage to implant • No particulate >0.02mm² per tappi chart	Pass
Secondary Wind Diameter	90%/90%	22	±0.5mm for 1mm size	Pass
Simulated Use	90%/90%	22	All ratings ≥3	Pass
Detachment	90%/80%	11	All units detach with a rating of ≥3	Pass
Coil/Coupler Weld Tensile	90%/80%	11	0.080 lb minimum	Pass
Spring Constant	90%/80%	11	spring constant greater than .09 oz/in	Pass

With the exception of the OD and length of the implant coil, the additional VFC model is essentially the same as the cleared predicate devices. There are no changes to material, intended use, principal of operation, or sterilization method. . Any differences in technological characteristics do not introduce any new issues of safety or effectiveness. In vitro testing was performed to assess the physical, mechanical, and functional performance of the subject device. The test protocols and acceptance criteria for the subject devices were identical to those of the predicate devices. The subject devices met the same acceptance criteria as the predicate devices. The results of the testing demonstrated that the VFC in the additional size is substantially equivalent to the predicate device. Test protocols and reports are on file at MicroVention.

SECTION/ECOPY PDF FILE# 018

PACKAGING, STERILIZATION AND SHELF LIFE

Packaging Components	1. Introducer Sheath: HDPE 2. Dispenser Coil: Polyethylene 3. Pouch: Polyester/Tyvek 4. Carton Box: Bleached Sulfate	
Method of Supplying	Sterile and single use.	
Sterility Validation Method	ANSI/AAMI/ISO 11137-1; 2006, Medical Devices- Sterilization of Health Care Products Radiation Part 1 – Requirements For Development, Validation and Sterilization Process for Medical Devices	
Sterilization Method	Electron beam or gamma radiation 25-40 kGy	
Sterility Assurance Level	(SAL) – 10^{-6}	
Contract Sterilization	Beam One (e-beam) 9020 Activity Road, Suite D San Diego, CA 92126	Sterigenics (gamma) 344 Bonnie Circle. Corona, CA 92880

The packaging configuration and sterilization method for the VFC line extension is the same as the predicate devices. No changes in materials or other design attributes have been made to subject coils. Additionally, the modifications to the introducer sheath and packaging hoop do not necessitate the performance of additional or repeat packaging qualification, sterilization revalidation or shelf life testing.

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

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

t = Accelerated Exposure Time (Days)

q = Acceleration Factor (Coefficient of Aging)

$$y = \frac{\text{Elevated Storage Temp (°C)} - \text{Ambient Storage Temp (22 °C)}}{10}$$

Test protocols and reports are on file at MicroVention.

SECTION/ECOPY PDF FILE# 019

BIOCOMPATIBILITY

Biocompatibility studies were not repeated as the subject devices are made from the same material and using the same processes as those utilized in the fabrication of the predicate devices. The biological safety of the predicate coils has previously been verified in accordance with the ISO10993-1, Biological Evaluation of Medical Devices. The testing was performed by independent laboratories. Test protocols and reports are on file at MicroVention.

SECTION/ECOPY PDF FILE# 020

QUALITY SYSTEM COMPLIANCE

MicroVention MCS products are designed, developed and tested in accordance with the MicroVention Design and Development procedure and with the MicroVention internal quality system procedure for risk management. Possible hazards and associated risk related to the device modification and clinical usage of the device were identified, examined and found to be acceptable after the implementation of the mitigation measures such as physician training program, labeling warnings and instructions for use.

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. The MicroVention facility is US FDA registered as well as licensed by the California State Department of Health.

Barlow, Lenny *

From: Barlow, Lenny *
Sent: Wednesday, September 25, 2013 3:14 PM
To: 'laraine.pangelina@microvention.com'
Cc: DCCLetters
Subject: k132317 Correspondence
Attachments: k132317.pdf

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

COVER SHEET MEMORANDUM

*****NOTE: This form is OPTIONAL for holds, and REQUIRED for final decisions*****

From: Reviewer Name __Jeffrey Toy, Ph.D.__

Subject: 510(k) Number ___K132317/S001__

To: The Record

Please list CTS decision code ___SE_____

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

o Hold (Additional Information or Telephone Hold).

X Final Decision (**SE**, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- o NO — NSE for lack of predicate
- o NI — NSE for new intended use
- o NQ — NSE for new technology that raises new questions of safety and effectiveness
- o NU — NSE for new intended use AND new technology raising new questions of safety and effectiveness
- o NP — NSE for lack of performance data
- o NS — NSE no response
- o NL — NSE for lack of performance data AND no response
- o NM — NSE pre-amendment device call for PMAs (515i)
- o NC — NSE post-amendment device requires PMAs
- o NH — NSE for new molecular entity requires PMA
- o TR — NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
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)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			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)?			X

Rev. 9/20/12 – added digital concurrence table

For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
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_____Class II_____HCG_____

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

Additional Product Codes:_____

Digital Signature Concurrence Table	
Branch Chief Sign-Off	Quynh T. Hoang -S 2013.09.20 15:59:29 -04'00'
Division Sign-Off	Joyce M. Whang -S 2013.09.20 16:55:55 -04'00'

K132317/S001

MicroVention
TERUMO

FDA CDRH DMC
AUG 23 2013
Received

August 22, 2013

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

(b)(4) Trade Secret Process - Product Specs

[redacted]

Dear Dr. Toy,

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Sincerely,

Laraine Pangelina
Sr. Regulatory Affairs Project Manager

Attached

- RA030001, Risk Control/Risk Assessment Analysis
- Revised 510(k) Summary
- Redlined 510(k) Summary comparing original to revised

MicroVention
TERUMO

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(b)(4) Trade Secret Process - Risk Analysis

SECTION/ECOPY PDF FILE# 006

510(K) SUMMARY

Trade Name: MicroPlex Coil System (MCS), VFC

Generic Name: Neurovascular Embolization Device

Classification: Class II, 21 CFR 882.5950

Date Submitted August 22, 2013

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

Contact: Laraine Pangelina

Predicate Device: MicroPlex Coil System (MCS) (K111451)

Indications for Use: The MicroPlex Coil System 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.

Device Description: The MCS VFC consists of an implantable coil made of bare platinum alloy. The MCS VFC implantable coils has a 3D shape in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Bench Test Summary:

Test	Results
Visual/Dimensional Inspection Perform visual inspection and measurments using device drawing	PASS, acceptance criteria met
Simulate Use Introduction, Tracking, Deployment, Compartmentalizing, Frame Movement, Microcatheter movement, Detachment, Overall Performance	PASS, acceptance criteria met
Detachment Test Confirm successful detachment according using V-Grip Detachment Controller during simulated use testing	PASS, acceptance criteria met
Coil-to-Coupler Weld Test Test the tensile strength of the coil/coupler weld	PASS, acceptance criteria met
Spring Constant Measure the spring constant force of the coil	PASS, acceptance criteria met
CONCLUSION: The results of the bench testing demonstrate that the subject device is safe and effective when used according to the instructions for use and performs equivalent to the predicate device. The testing was used in support of the risk analysis documentation for the subject device.	

Predicate / Subject Technological Comparison:

Feature	Predicate Devices	Subject Device
Coil shape	3D	Same
Coil OD (mm)	3 - 15	1
Restrained coil length (cm)	6 - 45	3
Main coil wire material	Platinum/Tungsten (92/8%) alloy	Same
Coupler Material	Platinum (90%)/ iridium (10%)	Same
Adhesive Material	DYMAX 1128-AM-VT UV Adhesive	Same
Stretch resistance filar material	Polyolefin Elastomer or PET	Same
Implant-to-pusher material	Polyolefin elastomer	Same
Delivery method	V-Trak delivery pusher	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, shipping carton	Same

Summary of Substantial Equivalence:

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

SECTION/ECOPY PDF FILE# 006

510(K) SUMMARY

Trade Name: MicroPlex Coil System (MCS), VFC

Generic Name: Neurovascular Embolization Device

Classification: Class II, 21 CFR 882.5950

Date Submitted August 22, 2013

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

Contact: Laraine Pangelina

Predicate Device: MicroPlex Coil System (MCS) (K111451)

Indications for Use: The MicroPlex Coil System 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.

Device Description: The MCS VFC consists of an implantable coil made of bare platinum alloy. The MCS VFC implantable coils has a 3D shape in various loop sizes and lengths. The coil is attached to a V-Trak delivery pusher. The proximal end is inserted into a hand held battery powered V-Grip Detachment Controller (sold separately). The implant segment detaches upon activation of the Detachment Controller.

Bench Test Summary:

Test	Results
Visual/Dimensional Inspection Perform visual inspection and measurments using device drawing	PASS, acceptance criteria met
Simulate Use Introduction, Tracking, Deployment, Compartmentalizing, Frame Movement, Microcatheter movement, Detachment, Overall Performance	PASS, acceptance criteria met
Detachment Test Confirm successful detachment according using V-Grip Detachment Controller during simulated use testing	PASS, acceptance criteria met
Coil-to-Coupler Weld Test Test the tensile strength of the coil/coupler weld	PASS, acceptance criteria met
Spring Constant Measure the spring constant force of the coil	PASS, acceptance criteria met
CONCLUSION: The results of the bench testing demonstrate that the subject device is safe and effective when used according to the instructions for use and performs equivalent to the predicate device. The testing was used in support of the risk analysis documentation for the subject device.	

~~**Bench Test Summary:**~~

~~Test~~	~~Result~~
~~Visual/Dimensional Inspection~~	~~Met established criteria~~
~~Simulated Use~~	~~Met established criteria~~
~~Detachment Test~~	~~Met established criteria~~
~~Coil to Coupler Weld Tensile~~	~~Met established criteria~~
~~Spring Constant~~	~~Met established criteria~~

Predicate / Subject Technological Comparison:

Feature	Predicate Devices	Subject Device
Coil shape	3D	Same
Coil OD (mm)	3 - 15	1
Restrained coil length (cm)	6 - 45	3
Main coil wire material	Platinum/Tungsten (92/8%) alloy	Same
Coupler Material	Platinum (90%)/ iridium (10%)	Same
Adhesive Material	DYMAX 1128-AM-VT UV Adhesive	Same
Stretch resistance filar material	Polyolefin Elastomer or PET	Same
Implant-to-pusher material	Polyolefin elastomer	Same
Delivery method	V-Trak delivery pusher	Same
MRI compatibility	Yes	Yes
Method of supply	Sterile, single use	Same
Packaging configuration	Dispenser coil, pouch, shipping carton	Same

Summary of Substantial Equivalence:

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