

510(k) Summary

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Reverse Medical Corporation is providing the summary of Substantial Equivalence for the Reverse Medical MVP™ Micro Vascular Plug System (MVP-5).

Device Trade or Proprietary Name

Reverse Medical MVP™ Micro Vascular Plug System

Sponsor /Applicant Name and Address

Reverse Medical Corporation
13700 Alton Parkway
Suite 167
Irvine, CA 92618

Sponsor Contact Information

Linda D'Abate
Reverse Medical
Vice President, RA/CA/QA

Date of Preparation of 510(k) Summary

October 25, 2013

Device Common/Usual or Classification Name

Device Embolization, Vascular (Product Code: KR D)

Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Device	Manufacturer	510(k) Number
Reverse Medical MVP™ Micro Vascular Plug System (MVP-3)	Reverse Medical™ Corporation Irvine, CA	K123803

Device Description

The Reverse Medical Micro Vascular Plug (MVP) is a micro vascular occlusion device comprised of a detachable embolic plug attached to a composite delivery wire and designed for delivery via a micro-catheter (0.027" ID). The MVP is a self-expandable, ovoid-shaped device made from Nitinol with an ePTFE partial cover. The device is secured at both ends with platinum marker bands. The Reverse Medical MVP is intended to reduce or occlude vascular blood flow of vessels having a diameter of 3.0 – 5.0mm.

The proximal marker band attaches to a delivery wire that pushes the device through a commercially available catheter to the intended treatment site. The Reverse Medical Detachment Box regulates detachment of the implant device from the delivery wire by electrolytic means during deployment, and monitors, detects, signals and measures the time of detachment. The Reverse Medical Cable Set – 275

cm length (Model RMCS – 2.75US) is provided sterile. The cable set connects to the Detachment Box through a bayonet type dual pin connector that ensures correct polarity. The Reverse Medical Cable Set and Detachment Box will be sold separately. One 9-volt battery and a sterile needle (20 G or 22 G) will also be needed for use with the Reverse Medical Micro Vascular Plug (MVP).

Intended Use

The Reverse Medical MVP is intended for use to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Comparison to Predicate Device

	New Device	Predicate Device
	Reverse Medical MVP-5 System	Reverse Medical MVP-3 System
510(k) No.	K123803 Class II KRD 870:3300	K123803 Class II KRD 870:3300
Indication for use	Indicated for use to obstruct or reduce the rate of blood flow in the peripheral vasculature.	Indicated for use to obstruct or reduce the rate of blood flow in the peripheral vasculature.
Method of Placement	Delivery wire through a 0.027" ID microcatheter.	Delivery wire through a 0.021" ID microcatheter.
Radiopaque markers	Platinum marker bands at each end	Platinum marker bands at each end
Proximal End Configuration	Proximal marker band and attachment for pusher wire	Proximal marker band and attachment for pusher wire
Detachment System	Yes - Electrolytic	Yes - Electrolytic
Battery Operated	Yes	Yes

Summary of Non-Clinical Data

Biocompatibility and Sterilization

The device was characterized as an implant, internal communicating device, which contacts circulating blood for exposure ≥ 30 days.

The Reverse Medical MVP materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1 guidelines "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The Reverse Medical MVP successfully passed all of the following biocompatibility tests, demonstrating that the materials are biocompatible:

Test Result Summary

Test	Results/Acceptance
Cytotoxicity	Non-Cytotoxic
Kligman Maximization Sensitization Test	Non-Sensitizing
Intracutaneous Injection	Non-Irritant
Systemic Injection	Non-Toxic
Material-Mediated Pyrogenicity	Non-Pyrogenic
Genotoxicity/Mutagenicity	Non-Mutagenic
In Vitro Mouse Lymphoma Assay	Non-Mutagenic
In Vivo Mouse Lymphoma	Non-Mutagenic
Hemolysis	Non-Hemolytic
Complement Activation C3a and SC5ba-9	No greater biological response than corresponding control
Inactivated Partial Thromboplastin Time	Minimal, passed acceptance criteria
Platelet and Leukocyte Counts	Non-activator, passed acceptance criteria
Muscle Implantation	Test articles: No range or acceptable level established.
	Intramuscular Implantation- 4 and 13 week, passed acceptance criteria

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6} .

Design Verification (Bench-Top Testing)

The physical, mechanical, and performance testing of the Reverse Medical MVP System demonstrate that the product is substantially equivalent to the currently marketed predicate devices. Design verification testing was conducted to evaluate the physical and mechanical properties of the Reverse Medical MVP. All studies were conducted in accordance with Reverse Medical Design Control procedures. All testing was performed on units that were sterilized and met all inspection criteria. Tests on the Reverse Medical MVP System included:

Verification and Test Summary

- Visual Inspection
- Dimensional Inspection
- Tensile Strength
- USP Particulate
- Radial Force
- Microcatheter Compatibility
- Detachment Time
- Torque Strength
- Plug Foreshortening
- Nickel Release
- Corrosion Resistance (potentiodynamic and galvanic)
- Flow Occlusion/Reduction
- Magnetic Resonance Compatibility
- Labeling
- Packaging
- Shelf Life
- Sterility
- Biocompatibility
- Detachment Box and Cable Set

All tests performed passed successfully. The physical, mechanical, and performance testing of the Reverse Medical MVP System demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate devices

Substantial Equivalence

The performance of the Reverse Medical MVP-5 System demonstrates that the product is substantially equivalent to the performance of the predicate devices. The equivalence was shown through comparison of component materials and specifications, performance, biocompatibility testing, animal testing, and sterilization validation.

The Reverse Medical MVP-5 System is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the predicate devices. Differences between the devices do not raise any significant issues of safety or effectiveness.



November 27, 2013

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

Reverse Medical Corporation
C/O Jeffrey Valko, President & CEO
13700 Alton Parkway, Suite 167
Irvine, CA 92618

Re: K133282

Trade/Device Name: Reverse Medical Micro Vascular Plug (MVP-5) System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 25, 2013
Received: October 28, 2013

Dear Mr. Valko:

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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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,



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

Enclosure

Reverse Medical Corporation
Special 510(k): Device Modification

Attachment 2: Indication for Use Statement

510(k) Number (if known): K133282

Device Name: Reverse Medical Micro Vascular Plug (MVP-5)

Indication for Use:

The Reverse Medical Micro Vascular Plug (MVP-5) System is intended for use to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. R. Hillbren