Section 5

<table>
<thead>
<tr>
<th>Sponsor/Applicant:</th>
<th>Reverse Medical Corporation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13700 Alton Parkway, Ste. 167</td>
</tr>
<tr>
<td></td>
<td>Irvine, CA 92618</td>
</tr>
<tr>
<td>Date Prepared:</td>
<td>May 17, 2014</td>
</tr>
<tr>
<td>Contact Person:</td>
<td>Jane Metcalf</td>
</tr>
<tr>
<td></td>
<td>Vice President, Quality, Regulatory and Clinical Affairs</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:jmetcalf@reversemed.com">jmetcalf@reversemed.com</a></td>
</tr>
<tr>
<td>Trade Name:</td>
<td>Reverse Medical® MVP® Micro Vascular Plug System</td>
</tr>
<tr>
<td>Common Name:</td>
<td>Vascular Embolization Device</td>
</tr>
<tr>
<td>Classification Name:</td>
<td>Vascular Embolization Device</td>
</tr>
<tr>
<td>Device Classification:</td>
<td>Class 2</td>
</tr>
<tr>
<td>Regulation Number:</td>
<td>870.3300 (product code: KRD)</td>
</tr>
<tr>
<td>Predicate Devices:</td>
<td>Reverse Medical MVP-3 (K123803) and Reverse Medical MVP-5 (K133282)</td>
</tr>
</tbody>
</table>

**Purpose of Submission**

The purpose of this special 510(k) submission is to obtain market clearance for two (2) modifications to the MVP System. The first is to replace the electrolytic detachment method with a mechanical detachment method. The second is to reduce the length of the delivery wire from 180 cm to 160 cm.

**Indication for Use and Intended Use**

The Reverse Medical® Corporation MVP® Micro Vascular Plug System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

**Device Description**

Reverse Medical® MVP® Micro Vascular Plug System consists of a micro vascular occlusion plug that is attached to a composite delivery wire and is intended to be delivered to the treatment site through a catheter. The MVP occlusion plug is a self-expandable, ovoid-shaped frame made from nitinol and incorporates a PTFE cover over the proximal portion of the ovoid. The plug device is secured at both ends with platinum marker bands. The proximal marker band is attached to a delivery wire that is used to push the plug device through a commercially available catheter to the intended treatment site. After satisfactory deployment of the plug device at the treatment site, the implant is detached from the delivery wire by rotating the wire counter clockwise.

**Technical Characteristics**

The modified devices have the same technological characteristics as the predicate devices except for the detachment method and length of delivery wire. The mechanical
detachment method eliminates the need for a software controlled detachment box and cables. Table 5-1 compares characteristics of the modified devices to the predicates.

<table>
<thead>
<tr>
<th>Feature</th>
<th>K123803 MVP-3 Predicate</th>
<th>K133282 MVP-5 Predicate</th>
<th>Subject of this Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>To obstruct or reduce the rate of blood flow in the peripheral vasculature.</td>
<td>To obstruct or reduce the rate of blood flow in the peripheral vasculature.</td>
<td>To obstruct or reduce the rate of blood flow in the peripheral vasculature.</td>
</tr>
<tr>
<td>Materials of Construction</td>
<td>Nitinol, PTFE, Platinum, SS 301, Solder, Polypropylene sheath, Urethane, Cyanoacrylate</td>
<td>Nitinol, PTFE, Platinum, SS 301, Solder, Polypropylene sheath, Urethane, Cyanoacrylate</td>
<td>Nitinol, PTFE, Platinum, Solder, Polypropylene sheath, Urethane Cyanoacrylate</td>
</tr>
<tr>
<td>Plug (Implant) description</td>
<td>Self-expandable, ovoid shaped frame with a PTFE cover over the proximal portion</td>
<td>Self-expandable, ovoid shaped frame with a PTFE cover over the proximal portion</td>
<td>Self-expandable, ovoid shaped frame with a PTFE cover over the proximal portion</td>
</tr>
<tr>
<td>Plug Diameter, Unconstrained</td>
<td>5.3 mm</td>
<td>6.5 mm</td>
<td>5.3 mm</td>
</tr>
<tr>
<td>Plug Length, Unconstrained</td>
<td>12 mm</td>
<td>12 mm</td>
<td>12 mm</td>
</tr>
<tr>
<td>Target Vessel Diameter</td>
<td>1.5-3.0 mm</td>
<td>3.0-5.0 mm</td>
<td>1.5-3.0 mm</td>
</tr>
<tr>
<td>Method of Placement</td>
<td>Delivery wire through a 0.021&quot; ID Microcatheter</td>
<td>Delivery wire through a 0.027&quot; ID Microcatheter</td>
<td>Delivery wire through a 0.021&quot; to 0.027&quot; ID Microcatheter</td>
</tr>
<tr>
<td>Radiopaque Markers</td>
<td>Platinum marker bands at each end of the plug</td>
<td>Platinum marker bands at each end of the plug</td>
<td>Platinum marker bands at each end of the plug</td>
</tr>
<tr>
<td>Proximal End of Plug Config.</td>
<td>Proximal marker band attached to delivery wire</td>
<td>Proximal marker band attached to delivery wire</td>
<td>Proximal marker band attached to delivery wire</td>
</tr>
<tr>
<td>Delivery Wire Length</td>
<td>180 cm</td>
<td>180 cm</td>
<td>160 cm</td>
</tr>
<tr>
<td>Detachment System</td>
<td>Electrolytic</td>
<td>Electrolytic</td>
<td>Mechanical</td>
</tr>
<tr>
<td>Sterilization Process</td>
<td>EO</td>
<td>EO</td>
<td>EO</td>
</tr>
<tr>
<td>Accessories</td>
<td>Electrolytic Box and Cables</td>
<td>Electrolytic Box and Cables</td>
<td>Torquer</td>
</tr>
</tbody>
</table>
Performance Tests – Non-clinical

Due to the change in detachment method and delivery wire length the following design verification tests 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:

- Dimensional Inspection
- Visual Inspection
- Microcatheter Compatibility within "Simulated Use Vascular Model"
  - Flexibility within microcatheter
  - Delivery wire kinking assessment
  - Multiple deployments and withdrawals through the microcatheter
  - Force required to deploy and retract device within the microcatheter
- Detachment Evaluations
  - Number of turns required to detach
  - Torque strength of detachment junction
- Galvanic Corrosion per ASTM G71
- MRI Compatibility per ASTM F-2503
- Package Integrity and Shelf-life

All tests successfully passed acceptance criteria. This demonstrates that the modified devices meet the product specification.

Basis for Determination of Substantial Equivalence

Upon reviewing the performance data and comparing intended use, design, materials, principle of operation and overall technological characteristics, the modified Reverse Medical MVP System is determined to be substantially equivalent to the currently marketed Reverse Medical MVP System. Differences between the systems do not raise any issues of safety or effectiveness.
June 18, 2014

Reverse Medical Corporation
% Jane Metcalf
VP, Quality Assurance, Regulatory and Clinical Affairs
13700 Alton Parkway, Suite 167
Irvine, California 92618

Re: K141313
Trade/Device Name: MVP Micro Vascular Plug System
Regulation Number: 21 CFR 870.3300
Regulation Name: Device Embolization, Vascular
Regulatory Class: II
Product Code: KRD
Dated: May 16, 2014
Received: May 20, 2014

Dear Ms. Metcalf,

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 Industry and Consumer Education 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" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Kenneth J. Cavanagh -S

for

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

Enclosure
510(k) Number (if known)
K141313

Device Name
Reverse Medical(R) Corporation MVP(R) Micro Vascular Plug System

Indications for Use (Describe)
The Reverse Medical(R) Corporation MVP(R) Micro Vascular Plug System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

Type of Use (Select one or both, as applicable)

☑ Prescription Use (Part 21 CFR 801 Subpart D)  ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)
Kenneth J. Cavanaugh -S

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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