K130858

REVERSE MEDICAL™

# 510(k) Summary according to 807.92

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 Microcatheter-027.

## 5.1 Sponsor /Applicant Name and Address

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

## 5.2 Sponsor Contact Information

Linda D'Abate, Vice President RA/CA/QA
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OCT 11 2013

## 5.3 Date of Preparation of 510(k) Summary

October 4, 2013

## 5.4 Device Trade or Proprietary Name

Reverse Medical Microcatheter-027

## 5.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY) (21 CFR.870. 1250)and Catheter, Infusion (Product Code KRA) (21 CFR 870.1210) and Diagnostic Intravascular Catheter (DQO, 21CFR870.1200)

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

| Name of Predicate Devices | Name of Manufacturer (City, State) | 510(k) Number |
|---|---|---|
| Headway™ 27 Microcatheter | MicroVention, Inc. Tustin, CA | K110813 |
| Excelsior® XT-27™ Microcatheter | Stryker Neurovascular Fremont, CA | K113778 |
| Reverse Medical Microcatheter-021 | Reverse Medical Corp. Irvine, CA | K122684 |

## 5.7 Device Description

The Reverse Medical Microcatheter-027 is a single lumen, flexible, variable stiffness composite catheter. The catheter shaft has a hydrophilic coating to reduce friction during use. The Reverse Medical Microcatheter-027 dimensions are included on the individual device labels. The Reverse Medical Microcatheter-027 inner lumen can accommodate guidewires up to 0.025 inches inner diameter to

access distal tortuous vasculature. Dual radiopaque markers at the distal portion of the catheter facilitate fluoroscopic visualization.

Each Reverse Medical Microcatheter-027 is provided with accessories, which include a shaping mandrel and peel away introducer within a Tyvek™ pouch.

The shaping mandrel allows the catheter tip to be steam shaped by the physician for proper adjustment to the anatomy prior to use. Test data is presented in this submission for both the 027 and 021 Reverse Medical Microcatheters to support the inclusion of the shaping mandrel and the peel away introducer.

The Reverse Medical Microcatheter-027 incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter is provided sterile, non-pyrogenic, and is intended for single use only.

### 5.8 Intended Use

The Reverse Medical Microcatheter-027 is intended for use in neuro, peripheral, and coronary vasculature for the infusion of diagnostic agents such as contrast media, and therapeutic agents such as inclusion coils.

## 5.9 Comparison to Predicate Devices

| | **MicroVention Headway™ 27 Microcatheter** | **Excelsior® XT-27™ Microcatheter** | **Reverse Medical Microcatheter-021** | **Reverse Medical Microcatheter-027** |
|---|---|---|---|---|
| 510(k) Number | K110813 | K113778 | K122684 | TBD |
| Classification | Class II, DQY | Class II, DQY | Class II, DQY and KRA | Class II, DQY and KRA |
| Indication | Intended for use in the peripheral, coronary and neurovasculature for the infusion of diagnostic agents, such as contrast media and therapeutic agents such as occlusion coils. | Intended to assist in delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid intervenetional devices (such as stents) intended for use in the neurovasculature and with a catheter of 0.027" I.D. | Intended for use in neuro, peripheral and coronary vasculature for the infusion of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils. | Intended for use in neuro, peripheral and coronary vasculature for the infusion of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils. |
| Shaft Materials | Coaxial lumen braided shaft variable stiffness catheter with radiopaque marker on distal end. | Semi-rigid proximal shaft that transitions into the flexible distal shaft with single or dual radiopaque markers at the distal end. | Single lumen, wire reinforced shaft, variable stiffness catheter with dual radiopaque markers on distal end. | Single lumen, wire reinforced shaft, variable stiffness composite catheter with dual radiopaque markers on distal end. |
| Proximal End Configuration | Luer Hub | Luer Hub | Luer Hub | Luer Hub |
| Radiographic markers/radi opacity | Dual radiopaque markers at distal tip. | Single or dual radiopaque markers at distal end of shaft. | Dual radiopaque markers at distal tip. | Dual radiopaque markers at distal tip. |
| Packaging | Polyethylene hoop and PET/PE/Tyvek pouch inside SBS carton. | Polyethylene hoop and PET/PE/Tyvek pouch inside SBS carton. | Polyethylene hoop and PET/PE/Tyvek pouch inside SBS carton. | Polyethylene hoop and PET/PE/Tyvek pouch inside SBS carton. |
| Sterilization | EtO | EtO | EtO | EtO |
| Peel Away introducer | | Yes | Yes (data presented in this submission | Yes |
| Catheter Tip Shaping Mandrel | Yes | Yes | Yes (data presented in this submission) | Yes |

## 5.10 Summary of Non-Clinical Data

### *5.10.1 Biocompatibility and Sterilization*

The Reverse Medical Microcatheter-027 is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24 hours). Results of the testing demonstrate that the blood-contacting materials are biocompatible.

Blood-contacting 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 Microcatheter-027 successfully passed all of the following biocompatibility tests:

| **Test** | **Results** | **Conclusion** |
|---|---|---|
| Cytotoxicity<br><br>L929 MEM Elution Test | MEM Elution test scored a grade 0 (No cell lysis) per ISO 10993-5. | Non-Cytotoxic |
| Sensitization<br><br>Kligman Maximization | Sensitization test scored a grade 0 (no visible change) per ISO 10993-10 | Non-Sensitizing |
| Systemic Toxicity (Acute)<br><br>ISO Acute Systemic Injection Test | Acute Systemic Injection Test Articles scored 0 with no toxicity or animal weight loss for both the cottonseed oil and saline extracts per ISO 10993-11 | Non-Toxic |
| Hemocompatibility:<br><br>Complement Activation | Under the conditions of the C3a assay, the test article exhibited activation at 9421 ng/ml. This was 5.8%of the normalized C3a concentration produced by CVF. Under the conditions of the SC5b-9 assay, the test article exhibited activation at 8836 ng/ml. This was 0.1%of the normalized SC5b-9 concentration produced by CVF. All biomaterials have the potential to affect the make-up of the complement activation components of the blood. | No greater biological response than corresponding control |

| | | |
|---|---|---|
| Hemolysis | The test article with negative control exhibited a hemolytic grade score of zero and is considered non-hemolytic. | Non- Hemolytic |
| Inactivated Partial Thromboplastin Time | The negative and positive controls met the criteria for a valid assay. The variance between duplicate readings was less than 15%. The clotting times were as follow:<br><br>Positive control: 107 seconds<br><br>Negative control: 300 seconds<br><br>Reference material: 300 seconds<br><br>Test Article: 290 seconds<br><br>The test article is considered to be a minimal activator of the intrinsic coagulation pathway. The test article was considered to pass the test. | Non Activator |
| *In vivo* Thrombogenicity | Implantation of the test and control devices resulted in no adverse effects or clinical signs. | Non-Thrombogenic |
| Pyrogenicity<br><br>USP Material Mediated Rabbit Pyrogen Test | Material-mediated pyrogenicity test was non-pyrogenic with no individual rabbit at any time having a temperature rise of greater than or equal to 0.5 deg. C per ISO 10993-11 | Non- Pyrogenic |
| EtO Residuals<br><br>Ethylene Oxide and Ethylene Chlorohydrins Residuals | ETO residuals met the criteria in accordance with ISO 10993-7 Part 7 | Passed, acceptable limits |
| Genotoxicity/Bacterial Reverse Mutation | A statistically significant increase in the number of revertant colonies was not observed with the test article extracts as compared to the negative controls in both non-activated and S9 activated conditions. | Non-Mutagenic |

| | | |
|---|---|---|
| Genotoxicity – Mouse lymphoma | The test article extracts (saline and DMSO) did not produce significantly more revertant colonies than the negative controls. | Non-Mutagenic |
| Genotoxicity – In vivo micronucleus | There was no statistically significant increase in the number of micronucleus in the test article extract (saline and sesame oil) vs. negative control group. | Non-Mutagenic |

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 $10^{-6}$.

*5.10.2 Design Verification (Bench-Top Testing)*

The physical, mechanical, and performance testing of the Reverse Medical Microcatheter-027 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 Microcatheter-027 with and without steam-shaping capabilities. 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 Microcatheter-027 included:

| Test Descriptions | Acceptance Criteria | Requirements | Pass/Fail |
|---|---|---|---|
| Dimensional/Visual Inspection | Per test protocol rev B | Pass/Fail | Pass |
| Tip Buckling Test | Peak Force Perform the same or better than the predicate devices | 95/90 | Pass |
| Coating Lubricity Test | Frictional force | 95/90 | Pass |
| | Coating Length | Pass/Fail | Pass |
| Flexibility/Shaft Stiffness Test | The distal tip and proximal shaft flexibility should perform comparably or better than the predicate | Pass/Fail | Pass |
| Priming Volume Test | For comparison to predicate | Equal to or better than predicate | Pass |
| Flow Rate Test | For comparison to predicate | Equal to or better than predicate | Pass |
| Guidewire Compatibility Test | Free movement of appropriately sized guidewires<br>Frictional force | 95/90 | Pass |

| | | | |
|---|---|---|---|
| Guide Catheter Compatibility Test | Free movement inside an appropriately sized Guide Catheter. Frictional force measurement | 95/90 | Pass |
| Catheter Air Leakage Test –per ISO 10551-1 | Per ISO 10551-1 | Pass/Fail | Pass |
| Catheter Liquid Leakage Test | No leaks in accordance with protocol | Pass/Fail | Pass |
| Dynamic Pressure Test | No leaks due to dynamic pressure test.<br>Peak Pressure: | Pass/Fail | Pass |
| Static Pressure Test | Burst pressure in accordance with protocol | 95/90 | Pass |
| Kink Resistance Test | Distal kink resistance | 95/90 | Pass |
| | Medial/proximal: for characterization purposes. | N/A | Pass |
| Torque Strength Test | X revolutions without failure. | Pass/Fail | Pass |
| Corrosion Resistance | No corrosion on metallic components. | Pass/Fail | Pass |
| USP Particulate Testing | Report total of particles. Compare to predicate devices. | USP 788 | Pass |
| Tensile Strength | Distal/medial ; medial/proximal<br>Proximal/hub<br>Proximal/hub | 95/90 | Pass |

The physical, mechanical, and performance testing of the Reverse Medical Microcatheter-027 demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate devices

***In vitro* Test Results for Reverse Microcatheter-027 Without Steam-Shaping Capabilities**

| Test Descriptions | Acceptance Criteria | Requirement | Pass/Fail |
|---|---|---|---|
| Navigation/ Accessibility/ Pushability | Comparable to predicate devices | Pass/Fail | Pass |
| Micro-devices Compatibility | Comparable to predicate devices | Pass/Fail | Pass |

**Performance/Functional Verification Test Results for Reverse Microcatheter-027 and 021 With Steam-Shaping Capabilities**

| Test Descriptions | Acceptance Criteria | Requirements | Pass/Fail |
|---|---|---|---|
| Dimensional and Visual Inspection | Per test protocol rev B. | Pass/Fail | Pass |
| Steam Shaping Capabilities | No Damage<br>Shape Inspection: at various angles | Pass/Fail | Pass |
| Coating Lubricity Test – Post Steam Shaping Test | Frictional force | Pass/Fail | Pass |
| Static Pressure Test – Post Steam Shaping Test | Burst pressure | 95/90 | Pass |
| Tensile Strength – Post Steam Shaping Test | Distal/Medial<br>Medial/Proximal<br>Proximal/Hub | 95/90 | Pass |

***In vitro* Bench Test Results for Reverse Microcatheter-027 and 021 Post Steam-Shaping**

| | | | |
|---|---|---|---|
| Navigation/ Accessibility/ Pushability | Comparable to predicate | Pass/Fail | Pass |
| Micro-devices Compatibility | Can allow uses of other micro-devices, in simulated flow model. | | |

## 5.11 Substantial Equivalence

The performance of the Reverse Medical Microcatheter-027 with and without steam-shaping capabilities in this submission 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, and sterilization validation.

The Reverse Medical Microcatheter-027 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.

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

October 11, 2013

Reverse Medical Corporation
Mr. Jeffrey Valko
President/Chief Executive Officer
13700 Alton Parkway, Suite 167
Irvine, CA 92618

Re: K130858
Trade/Device Name: Reverse Medical Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY, KRA and DQO
Dated: September 6, 2013
Received: September 6, 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.

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: K130858

Device Name: Reverse Medical

Indications For Use:

The Reverse Medical Microcatheter-027 is intended for use in neuro, peripheral and coronary vasculature for the infusion of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S