## Section 5

## 510(k) Summary

JUL 17 2012

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| **General Provisions** | Submitter Name:<br>Address:<br><br>Telephone Number:<br>Fax Number:<br>Contact Person:<br>Date of Preparation:<br>Registration Number: | Merit Medical Systems, Inc.<br>1600 West Merit Parkway<br>South Jordan, UT 84095<br>(801) 316-4932<br>(801) 316-4860<br>Casey Hughes<br>06/18/2012<br>1721504 |
| **Subject Device** | Trade Name:<br>Common/Usual Name:<br>Classification Name: | ReSolve® Biliary Locking Drainage Catheter<br>Biliary Drainage Catheter<br>Catheter, Biliary, Diagnostic |
| **Predicate Device** | Trade Name:<br>Common/Usual Name:<br>Classification Name:<br>Premarket Notification:<br>Manufacturer: | ReSolve® Biliary Drainage Catheter<br>Biliary Drainage Catheter<br>Catheter, Biliary, Diagnostic<br>K063733<br>Merit Medical Systems, Inc. |
| **Classification** | Class II<br>21 CFR § 876.5010<br>Gastroenterology/Urology | |
| **Intended Use** | The ReSolve® Biliary Locking Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system. | |

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| **Device Description** | The ReSolve® Biliary Locking Drainage Catheter consists of single lumen tubing with two suture holes and 17 to 18 drainage holes in the distal curve region. It is made from a biocompatible thermoplastic. A hydrophilic coating reduces entry site/catheter friction during placement. The components of the catheter allow initial placement using an over-the-wire technique. These include a metal stiffening cannula, flexible stiffening cannula, straightener, and repositioning tool. The pigtail straightener is provided to assist in feeding the guide wire through the catheter. Once the catheter position is established in the area to be drained, the pigtail is formed by retracting a suture which is looped from the hub, to the catheter tip and back to the hub. The hub incorporates a suture locking mechanism to retain the distal pigtail shape. It may be unlocked using the repositioning tool to allow repositioning or replacement of the catheter. A single radiopaque marker band is located proximal to the most proximal drainage hole to assist in accurate placement of the drainage holes in the biliary duct. |
| **Technological Characteristics** | The technological characteristics of the subject ReSolve Biliary Locking Drainage Catheter are substantially equivalent to those of the predicate device, the ReSolve Biliary Drainage Catheter, 510(k) K063733. |

**Safety & Performance Tests**

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the ReSolve Biliary Locking Drainage Catheter was conducted based on a risk analysis and based on the requirements of the following international standards:

- ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process,* and the FDA Modified ISO 10993 Test Profile
- ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-7:2008, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*
- ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ISO 10993-17:2002, *Biological Evaluation of Medical Devices – Part 17: Methods for the Establishment of Allowable Limits for Leachable Substances*
- ISO 10993-18:2005, *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials*
- USP 34 <151>:2011, United States Pharmacopeia 34, National Formulary 29, 2011. <151> Pyrogen Test.
- EN 1617:1997, *Sterile Drainage Catheters and Accessory Devices for Single Use*
- ASTM D4169-09:2009, *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM F 1980-07:2007, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
- ISO 2233:2000, *Packaging — Complete, Filled Transport Packages and Unit Loads — Conditioning for Testing*

The following is a list of all significant testing that was successfully completed:

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| **Safety & Performance Tests cont.** | <u>Design Verification</u><br>Conditioning<br>Dimensional<br>Drainage Hole Orientation<br>Marker Band/Hole Location<br>Tip Penetration<br>Hub Leak<br>Vacuum Test<br>Tubing Kink Test<br>Marker Band Adhesion<br>Hub Tensile Testing<br>Tubing Tensile Testing<br>Material Durability Testing<br>Bile Exposure Testing<br>Stiffening Cannula Friction Test<br><br><u>Biocompatibility Tests</u><br>Cytotoxicity<br>Irritation<br>Acute Systemic Toxicity<br>Pyrogenicity<br>Chemical Characterization |
| **Safety & Performance Tests cont.** | The results of the testing demonstrated that the subject ReSolve Biliary Locking Drainage Catheter met the pre-determined acceptance criteria applicable to the safety and efficacy of the device. |
| **Summary of Substantial Equivalence** | Based on the indications for use, design, and safety and performance testing, the subject ReSolve Biliary Locking Drainage Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the ReSolve Biliary Drainage Catheter, manufactured by Merit Medical Systems, Inc. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Casey Hughes
Manager, Regulatory Affairs
Merit Medical Systems, Inc.
1600 West Merit Parkway
SOUTH JORDAN UT 84095

JUL 17 2012

Re: K121832
Trade/Device Name: Resolve® Biliary Locking Drainage Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: June 18, 2012
Received: June 22, 2012

Dear Ms. Hughes:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

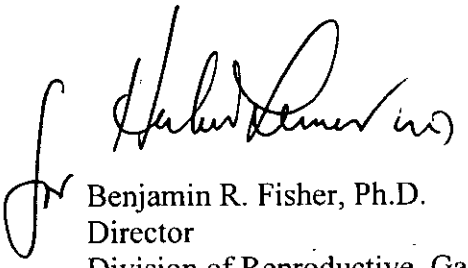
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

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



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

## Section 4

## Indications for Use

510(k) Number (if known): K121832

Device Name: ReSolve® Biliary Locking Drainage Catheter

Indications for Use:
The ReSolve® Biliary Locking Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121832