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

November 26, 2014

Merit Medical Systems, Inc.
Glenn Norton
Vice President, Regulatory Affairs
1600 West Merit Parkway
South Jordan, UT 84095

Re: K141408
Trade/Device Name: ReSolve® Biliary Locking Drainage Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Gastroenterology and Urology
Regulatory Class: Class II
Product Code: FGE
Dated: October 27, 2014
Received: May 28, 2014

Dear Clea Feight:

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" (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 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,

Herbert P. Lerner -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141408

Device Name
ReSolve Biliary Locking Drainage Catheter

Indications for Use *(Describe)*
The ReSolve Biliary Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 826-4019 (801) 316-4853 Clea Feight May 27, 2014 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	ReSolve® Biliary Locking Drainage Catheter Biliary Drainage Catheter Catheter, Biliary, Diagnostic
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	ReSolve® Biliary Locking Drainage Catheter Catheter, Biliary, Diagnostic K121832 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 876.5010 FDA Product Code: FGE Review Panel: Gastroenterology and Urology	
Intended Use	The ReSolve® Biliary Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system.	

Device Description	The ReSolve® Biliary Locking Drainage Catheter consists of single lumen tubing with 17 to 18 drainage holes (depending on the French size of the catheter) and a single dedicated suture hole. One of the drainage holes doubles as a suture hole. The tubing is made from a polyurethane material. A hydrophilic coating reduces entry site/catheter friction during placement. The catheter is offered in two drainage hole configurations. The RBC (long) configuration has a lesion gap (distance between the proximal pigtail and the distal shaft drainage hole) of 5 cm. The RBDC (standard) has a lesion gap of 2 cm. The components of the catheter allow initial placement using an over-the-wire technique. These include a metal stiffening cannula, flexible stiffening cannula, pigtail straightener and repositioning tool. The hubs of the flexible and metal stiffening cannula are color coded for catheter French size identification. The pigtail straightener is provided to assist in feeding the guide wire through the catheter. A dead end cap is included to prevent fluid from exiting the catheter after placement. 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 catheter tip then 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. In addition, the shaft of the catheter is printed with markings for the clinician to determine how deep the catheter is in the patient. The catheter is available in the same sizes 8.5F, 10F, 12F, and 14F with the same useable length, 40 cm, as the predicate device. The ReSolve® Biliary Locking Drainage Catheter is a single use device that is supplied sterile and non-pyrogenic. The device is marketed with the following components, depending on the product configuration: StayFIX® or Revolution™ catheter securement device.

	The technological characteristics of the subject ReSolve® Biliary Locking Drainage Catheter are substantially equivalent to those of the predicate device. The subject device has the same basic design as the predicate device in that it consists of single lumen tubing with drainage holes, hub, and suture locking mechanism and is provided with a metal stiffening cannula, flexible stiffening cannula, pigtail straightener, repositioning tool and dead end cap. The ReSolve® Biliary Locking Drainage Catheter is similar in clinical use and function to the predicate ReSolve® Biliary Locking Drainage Catheter.
Comparison to Predicate Device	The main difference is in the catheter shaft material and that the subject device is coated with a different hydrophilic coating on the outer surface of the catheter tubing. In addition, printed depth markings have been added to the catheter shaft and the location of the drainage holes has been modified to standardize the gap between the pigtail and the shaft holes (RBC versus RBDC) across all French sizes with adjustment of the marker band location to account for this change. The geometry of the tip has been modified slightly to have a longer taper. Minor changes have also been made to the colorant formulation (color additives) used in molding three of the accessory components of the device due to discontinuation notices from suppliers.

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 subject ReSolve® Biliary Locking Drainage Catheter was conducted based on the risk analysis and based on the requirements of the following recognized and unrecognized international standards: • EN 1617:1997, *Sterile drainage catheters and accessory devices for single use* • EN 1618:1997, *Catheters other than intravascular catheters -- Test methods for common properties* • ISO 11135-1 First Edition 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 FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995 • ISO 10993-3:2003, *Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity* • ISO 10993-5:2009*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* • ISO 10993-6:2007, *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation* • 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: Establishment of allowable limits for leachable substances* • ISO 10993-18:2005, *Biological evaluation of medical devices – Part 18: Chemical characterization of materials* • ISO 11607-1:2010, *Packaging for terminally sterilized medical devices* • ASTM D4169-09, *Standard Practice for Performance Testing of Shipping Containers and Systems* • United States Pharmacopeia Section <151>, USP 36 Pyrogen Testing, 2013-12-01 • United States Pharmacopeia Section <661>, USP 36 Physiochemical Tests for Plastics

Safety & Performance Tests cont.	<u>Performance Testing-Bench</u> • Cyclic Fatigue Testing • Material Improvement Chemical Testing • Optical Density/Radio-detectability • Curve Shape Visual • Product Dimensions – Useable Length • Product Dimensions – Marker Band to Pigtail Distance • Product Dimensions – Distal Shaft Hole to Pigtail Distance • Marker Band/Proximal Hole Location • Punched Holes Orientation and Number of Holes • Hydrophilic Coating Coverage/Adherence and Length • Guide Wire Passage Test • Flow Testing • Pigtail Pull Test • Tip Penetration Test • Cannula and Stiffener Insertion Test • Tip Geometry • Drainage Hole Tensile Test • Catheter Collapse • Tubing Kink Testing • Hub Leak/Liquid Ingress Test • Hub Tensile Test • Marker Band Transition • Ink Adherence • 14F Metal and Plastic Stiffening Cannula Hub Tensile Test and Visual Inspection • Pigtail Straightener Test <u>Biocompatibility</u> • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Genotoxicity • Implantation • Chemical Characterization
Summary of Substantial Equivalence	Based on the indications for use, design, 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 Locking Drainage Catheter, K121832.