DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2015

Merit Medical Systems Incorporated
Ms. Ileana Garcia
Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K151373
Trade/Device Name: Corvocet Coaxial Introducer
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG
Dated: May 20, 2015
Received: May 21, 2015

Dear Ms. Garcia:

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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K151373

Device Name
Corvocet Coaxial Introducer

Indications for Use *(Describe)*
The Corvocet Coaxial Introducer is intended for use as a guiding needle in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

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5.0 510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4187 (801) 316-4065 Ileana Garcia, Regulatory Affairs Specialist 20 May 2015 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Corvocet Coaxial Introducer Coaxial Introducer Biopsy Needle Kit II FCG 876.1075 Gastroenterology/Urology
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer: This predicate has not been subject to a design-related recall.	TruGuide® Disposable Coaxial Biopsy Needle Biopsy Needle Kit K936194 Bard Peripheral Vascular, Inc.
Reference Device	No reference devices were used in this submission.	
Device Description	The Merit Corvocet Coaxial Introducer is used as a guiding needle for a biopsy device obtaining core biopsy samples from soft tissues. It is a three-part disposable device consisting of the following: a stainless steel outer cannula with a female Luer lock hub and an echo-enhanced tip to aid with visibility under ultrasound; a stainless steel inner trocar attached to a unique trocar hub design that allows it to be released by squeezing both sides of the hub; and a flexible silicone slip ring-style depth stop that is color-coded for gauge identification and can be manually adjusted to maintain the depth of the coaxial introducer in a procedure. An optional stainless steel blunt stylet with hub can be included with 17G and 19G coaxial introducers. The blunt stylet may be used to manipulate through soft tissue and around vasculature or other organs to minimize the risk of unintentional damage to these areas. The Merit Corvocet Coaxial Introducer is supplied sterile and is single use only.	
Indications for	The Corvocet Coaxial Introducer is intended for use as a guiding	

Use	needle in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors. The Indications for Use statement for the Corvocet Coaxial Introducer is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use as a guiding needle in obtaining core tissue samples from soft tissue.
Comparison to Predicate Device	The technological characteristics of the subject Corvocet Coaxial Introducer are substantially equivalent to those of the predicate TruGuide® Disposable Coaxial Biopsy Needle. At a high level, the subject and predicate devices are based on the following same elements: • Clinical use • Labeling • Basic design • Principle of operation • Performance • Needle gauges The following differences exist between the subject and predicate devices: • Soft tissues • One-handed trocar removal • Materials
Performance Data	FDA guidance and recognized performance standards have been established for biopsy needle kit under Section 514 of the Food, Drug and Cosmetic Act. A battery of tests was performed based on the requirements of the below recognized performance standards and guidance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the proposed Corvocet Coaxial Introducer met the standards' established acceptance criteria applicable to the safety and efficacy of the device. Performance testing was conducted based on the risk analysis and based on the requirements of the following documents: • Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology • ISO 7864:1993 – Sterile hypodermic needles for single use • ISO 7864-2:1993 – Sterile hypodermic syringes and needles – Part 2: Specification for sterile hypodermic needles for single use • ISO 9626:1991 Amendment 1:2001– Stainless steel needle tubing for manufacture of medical devices

- ISO 594-1:1986 – Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 1: General requirements
- ISO 594-2:1998 – Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 2: Lock fittings
- ISO 6009:1992 – Hypodermic needles for single use – Color coding for identification
- ISO 11607-1:2006 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems
- ASTM D4169-09 – Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 2233:2001 – Packaging – Complete, filled transport packages and unit loads – Conditioning for testing
- ASTM F1980-11 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 11135:2014 – 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
- 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
- United States Pharmacopoeia 37, National Formulary 32 <151> Pyrogen Test, 2014.

The following performance data were provided in support of the substantial equivalence determination.

<u>Performance Testing – Bench</u>

- Dimensions
- Tensile of Joints – Needle-to-Hub
- Tensile of Joints – Trocar-to-Hub
- Tensile of Joints – Blunt Stylet-to-Hub
- Luer – Gauging
- Luer – Liquid Leakage
- Luer – Air Leakage
- Luer – Separation Force
- Luer – Unscrewing Torque
- Luer – Ease of Assembly
- Luer – Resistance to Overriding

	• Luer – Stress Cracking • Depth Stop • Introducer Visibility • Simulated Use **Biocompatibility testing** The biocompatibility evaluation for the Corvocet Coaxial Introducer was conducted in accordance with the FDA Blue Book Memorandum #G95-1 *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995, and the International Standard ISO 10993-1:2009 *Biological evaluation of medical devices − Part 1: Evaluation and testing within a risk management process* as recognized by FDA. The battery of testing included the following tests: • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Chemical Characterization
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Corvocet Coaxial Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the TruGuide® Disposable Coaxial Biopsy Needle, K936194.