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

March 25, 2016

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

Re: K153337
Trade/Device Name: Corvocet Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 25, 2016
Received: February 26, 2016

Dear Ms. Davis:

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,

Jennifer R. Stevenson -A

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)*
K153337

Device Name
Corvocet Biopsy System

Indications for Use *(Describe)*
The disposable Corvocet Biopsy System is intended for use in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

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:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4187
	Fax Number:	(801) 316-4065
	Contact Person:	Ileana Davis, Regulatory Affairs Specialist
	Date Prepared:	18 November 2015
	Registration Number:	1721504
Subject Device	Trade Name:	Corvocet Biopsy System
	Common/Usual Name:	Biopsy System
	Classification Name:	Instrument, Biopsy
	Device Class:	II
	Product Code:	KNW
	Classification Regulation:	CFR 876.1075
Predicate Device	Trade Name:	Max-Core® Disposable Core Biopsy Instrument
	Classification Name:	Instrument, Biopsy
	Premarket Notification:	K133948
	Manufacturer:	Bard Peripheral Vascular, Inc.
Device Description	Merit's Corvocet Biopsy System is a core needle biopsy device intended to obtain core biopsy samples from soft tissues. It is an automatic device that uses a spring coupled to a cutting needle to obtain full core soft tissue specimens. It has an echo-enhanced tip to aid with visibility under ultrasound, fully adjustable throw length (10-25mm) and depth markings on the needle. The device also features a light weight design, ergonomic grip, dual firing triggers, a ready indicator, and an optional safety interlock. The Corvocet Biopsy System is available in several needle gauge sizes and lengths to accommodate soft tissue biopsy needs. The top and rear firing triggers are color coded according to the various gauge sizes (e.g. yellow = 20G, pink = 18G, purple = 16G, and green = 14G). The biopsy system will be offered as stand-alone as well as paired with the Corvocet™ Coaxial Introducer. The Merit Corvocet Biopsy System is supplied sterile and is intended for single use only.	
Indications for Use	The disposable Corvocet Biopsy System is intended for use in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate,	

	spleen, breast, lung, lymph nodes and various soft tissue tumors. It is not intended for use in bone. The Indications for Use statement for the Corvocet Biopsy System 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 of obtaining core biopsy samples from soft tissues.
Comparison to Predicate Device	The technological characteristics of the subject Corvocet Biopsy System are substantially equivalent to those of the predicate Max-Core® Disposable Core Biopsy Instrument. 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 • Materials • Adjustable throw length
Performance Data	FDA guidance and recognized performance standards have been established for biopsy instrument 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 Biopsy System 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 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 – 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:

Performance Testing – Bench

- Dimensional verification
- Tensile of joints
- Adjustable throw accuracy
- Multiple Samples
- Cycle/Fatigue
- Device Visibility
- Ink adherence
- Simulated Use

The Corvocet Biopsy System met the acceptance criteria for all performance testing.

Biocompatibility testing
The biocompatibility evaluation for the Corvocet Biopsy System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing"* 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 Biopsy System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Max-Core® Disposable Core Biopsy Instrument, K133948.