March 12, 2018

Merit Medical Systems, Inc.
Ms. Angela Brady
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K180450
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 16, 2018
Received: February 20, 2018

Dear Ms. Brady:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180450

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.***

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
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Office of Chief Information Officer
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*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."*

# 510(k) Summary

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| **General Provisions** | Submitter Name: | Merit Medical Systems, Inc. |
| | Address: | 1600 West Merit Parkway<br>South Jordan, UT 84095 |
| | Telephone Number: | (801) 316-4818 |
| | Fax Number: | (801) 316-4878 |
| | Contact Person: | Ms. Angela Brady, MS<br>Senior Regulatory Affairs Specialist<br>abrady@merit.com |
| | Date of Preparation: | February 16, 2018 |
| | Registration Number: | 1721504 |
| **Subject Device** | Trade Name: | Corvocet Biopsy System |
| | Common/Usual Name: | Biopsy System |
| | Classification Name: | Instrument, Biopsy |
| | Regulatory Class: | II |
| | Product Code: | KNW |
| | 21 CFR §: | 876.1075 |
| | Review Panel: | 78 Gastroenterology/Urology |
| **Predicate Device** | Trade Name: | Corvocet Biopsy System |
| | Classification Name: | Instrument, Biopsy |
| | Regulatory Class: | II |
| | Product Code: | KNW |
| | 21 CFR §: | 876.1075 |
| | Premarket Notification: | K153337 |
| | Manufacturer: | Merit Medical Systems, Inc. |
| | Review Panel: | 78 Gastroenterology/Urology |

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| **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 wright design, ergonomic grip, dual firing triggers, a ready indicator, and an optional safety interlock.<br><br>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 Corvocet Biopsy System will be offered as a stand-alone as well as paired with the Corvocet™ Coaxial Introducer.<br><br>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.<br><br>There is no change in the Indications for Use Statement from the predicate to the subject device. |
| **Comparison to Predicate Device** | The technological characteristics of the subject Corvocet Biopsy System are identical to those of predicate device Corvocet Biopsy System. The subject device has the same basic design as the predicate device. The main difference between the subject and the predicate devices is the spacing of internal components were changed to capture and release biopsy samples. The comparison between the subject and predicate devices is based on the following:<br><br>• Same intended use<br>• Same indications for use<br>• Similar material types that meet ISO 10993 biocompatibility requirements<br>• Same sterilization methods<br>• Same fundamental technology/principal of operation/user interface |

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| **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:<br>• Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology<br>• FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" June 2016<br>• ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]*<br>• ISO 11135:2014, Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices<br>• ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]*<br>• AAMI TIR 28:2009, *Product adoption and process equivalency for ethylene oxide sterilization*<br>• ISO 11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1(2014)]*<br>• ISO 2233:2000, *Packaging – Complete, filled transport packages and unit loads – Conditioning for testing*<br>• ASTM D4169-14:2014, *Standard Practice for Performance Testing of shipping Containers and systems*<br>• ASTM F1980-07:2007, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (Reapproved 2011)*<br>• AAMI/ANSI ST72:2011/(R)2016, *Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing* |

**Safety & Performance Tests cont.**

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

Biocompatibility Testing

All materials of the subject device (excluding the spacer) are used in the legally marketed predicate Corvocet Biopsy System with the same intended use, patient contact, processing and sterilization methods. Therefore, no further biocompatibility testing is required for these materials. The spacer is categorized as having no direct or indirect contact with the human body.

The Corvocet Biopsy System is an Externally Communicating Device with Tissue Contact for a Limited (≤ 24 hour) Duration.

Performance Testing-Bench

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| Simulate Use – Biopsy Sample | To ensure the aspect of the biopsy sample is clinically acceptable. |
| Simulate Use – Multiple Samples | To measure the mass of a simulated tissue that is harvested from a biopsy. To confirm that the biopsy device can successfully retrieve biopsy samples multiple cycles. |
| Cycle / Fatigue | To ensure the device joints can withstand multiple cycles without device failure. |
| Device Diameter Compatibility | To evaluate device compatibility with corresponding coaxial introducer. |

The results of the testing demonstrated that the subject Corvocet Biopsy System met the predetermined acceptance criteria applicable to the safety and efficacy of the device.

**Summary of Substantial Equivalence**

Based on the indications for use, design, and performance testing conducted between the subject Corvocet Biopsy System and the predicate device, the Corvocet Biopsy System, meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Corvocet Biopsy System, K153337 manufactured by Merit Medical Systems, Inc.