August 28, 2020

Merit Medical Systems, Inc.
Niloufar Samimi
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K201166
Trade/Device Name: Temno Elite Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 30, 2020
Received: August 3, 2020

Dear Niloufar Samimi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter, Jr.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K201166

Device Name
Temno Elite Biopsy System

Indications for Use *(Describe)*
The Temno Elite Biopsy System is intended for use in obtaining biopsies from soft tissues such as liver, kidney,breast,prostate, spleen,lung,lymph nodes,thyroid,and various soft tissue masses. It is NOT intended for use in bone.
The Valved Coaxial Introducer Needle and Standard Coaxial Introducer Needles are intended for use as guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney,prostate,spleen, lung,lymph nodes,thyroid, and various soft tissue masses. 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.

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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) 208-4583 Contact Person: Niloufar Samimi Date Prepared: 26 April 2020 Registration Number: 1721504
Subject Device	Trade Name: Temno Elite Biopsy System Common/Usual Name: Biopsy System Classification Name: Instrument, Biopsy Regulatory Class: II Product Code: KNW 21 CFR §: 876.1075 Review Panel: Gastroenterology/ Urology
Predicate Device	**Premarket Notification Predicate #1:** Trade Name: Bard® Mission® Disposable Core Biopsy Instrument Classification Name: Instrument, Biopsy Premarket Notification: K171953 Manufacturer: Bard Peripheral Vascular, Inc **Premarket Notification Predicate #2:** Trade Name: Achieve Programmable Automatic Biopsy Systems Classification Name: Instrument, Biopsy Premarket Notification: K141552 Manufacturer: CareFusion These predicates have not been subject to a design-related recall.
Device Description	The subject device is a single use full core biopsy device. It is available in several gauge sizes and lengths. The device has printed gauge size indicator that is color coded according to the various gauge sizes (yellow= 20G, pink= 18G, purple= 16 G, green= 14G, and blue=12G. The needles have a protective sheath. The Temno Elite Biopsy system includes Biopsy device and has the option of including a Valved Coaxial Introducer Needle , or a Standard Coaxial Introducer Needle. The depth stop on both the Valved Coaxial

	Introducer Needle and the Standard Coaxial Introducer Needle is color coded to match the gauge size of the Temno Elite Biopsy system. The Temno Elite Biopsy System is supplies sterile and is intended for single use only.
Indications for Use	The Temno Elite Biopsy System is intended for use in obtaining biopsies from soft tissues such as liver, kidney, breast, prostate, spleen, lung, lymph nodes, thyroid, and various soft tissue masses. It is NOT intended for use in bone. The Valved Coaxial Introducer Needle and Standard Coaxial Introducer Needles are intended for use as guiding needle in obtaining core biopsy samples from soft tissue such as liver, kidney, prostate, spleen, lung, lymph nodes, thyroid, and various soft tissue masses. It is NOT intended for use in bone. 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 Temno Elite Biopsy System device are substantially equivalent to those of the predicate device #1 Bard® Mission® Disposable Core Biopsy and Reference Predicate Device #2, Achieve Programmable Automatic Biopsy. At a high level, the subject and predicate devices are based on the following same technological elements: • Clinical use • Labeling • Basic design • Principle of operation • Performance • Soft tissues • Adjustable throw lengths The following technological differences exist between the subject and predicate devices: • Needle gauges • Materials • Biopsy chamber geometry • Sample eject assist

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 Temno Elite 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:

- ANSI/AAMI/ISO 11135:2014 *, Sterilization of health care products – routine control of a sterilization process for medical devices*
- ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide residuals
- ISO 7864: 2016, Sterile hypodermic needles for single use - Requirements and test methods
- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 6009:2016, Hypodermic needles for single use - Color coding for identification
- ISO 2233:2000, Complete, filled transport packages and unit loads - Conditioning for testing
- ISO 80369-7:2019, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980:2016, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 10993-1:2018, *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 – Part10: Tests for irritation and skin sensitization*
- ISO 10993-11:2017, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- United States Pharmacopeia 42, National Formulary 37 (USP) <151> Pyrogen Test, 2019

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
- Device Visibility
- Simulated Use

Biocompatibility testing
The biocompatibility evaluation for the Temno Elite Biopsy System was conducted in accordance with the FDA Guidance Document "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process,'" (2016), and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," (2018) as recognized by FDA. The battery of testing included the following test:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity

The result of biocompatibility testing demonstrate that the subject device Temno Elite Biopsy System is considered biocompatible for its intended use.

Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject Temno Elite Biopsy System meets the requirements that are considered essential for its intended use and is substantially equivalent to the Predicate device #1 Bard Mission Disposable Core Biopsy Instrument, K171953 and Reference Predicate device #2 Achieve Programmable Automatic Biopsy, K141552.