K102273
pg 1 of 1

MERIT MEDICAL

MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PARKWAY
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PHONE 801-253-1600
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# 5.0 510(k) Summary

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| **General Provisions** | Submitter Name:<br>Address:<br><br>Telephone Number:<br>Fax Number:<br>Primary Contact:<br>Date of Preparation: | Merit Medical Systems, Inc.<br>1600 West Merit Parkway<br>South Jordan, UT 84095<br>(801) 208-4187<br>(801) 253-6905<br>Dan W. Lindsay<br>August 9, 2010 |
| **Subject Device** | Trade Name:<br>Common/Usual Name:<br>Classification Name: | To be assigned<br>Bipolar Coagulation Probe<br>Unit, electrosurgical, endoscopic (with or without accessories) |
| **Predicate Device** | Trade Name:<br>Classification Name:<br><br>Premarket Notification:<br>Manufacturer: | Merit Bipolar Coagulation Probe<br>Unit, electrosurgical, endoscopic (with or without accessories)<br>K912129<br>Merit Medical Systems, Inc. |
| **Classification** | Class II<br>21 CFR §876.4300<br>Gastroenterology/Urology | |
| **Intended Use** | The Bipolar Coagulation Probe is intended to be passed through an endoscope's working channel to provide hemostasis throughout the gastrointestinal tract. | |
| **Device Description** | The proximal end of the Merit Bipolar Coagulation Probe consists of a plug which connects to an electrosurgical generator and a luer flush hub which connects to an irrigation source. The plug comes in one of two configurations: a single or dual bipolar plug. The tubing from the plug encases a Teflon coated wire which is united with the flushing lumen from the luer in a Y connection. A single tube with the coated wire and flushing lumen leads from the Y connection to the distal probe tip. The distal end (tip) consists of uniformly spaced metal electrodes configured in a spiral fashion on the rounded ceramic tip. | |

SEP 07 2010

K 102273
pg 2 of 2

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| **Technological Characteristics** | The subject device has the same technological characteristics as the predicate device. Minor design changes were made to improve aesthetics, ergonomics and manufacturability of the device. |
| **Performance Testing** | The verification testing required by the risk analysis was completed and included the following tests: tensile, flow, leak, high frequency leakage, high frequency dielectric strength, mains frequency dielectric strength, wiring continuity, kink resistance and tip separation. Testing results met the predetermined acceptance criteria. |
| **Testing Conclusion** | The results of the testing performed demonstrate the subject device is as safe, as effective, and performs as well as or better than the predicate device. |
| **Summary of Substantial Equivalence** | Based on the indications for use, design, and safety and performance testing, the subject Merit Bipolar Coagulation Probe meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit Bipolar Coagulation Probe manufactured by Merit Medical Systems, Inc. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Dan W. Lindsay
Regulatory Affairs Specialist II
Merit Medical Systems, Inc.
1600 West Merit Parkway
SOUTH JORDAN UT 84095

SEP 07 2010

Re: K102273
Trade/Device Name: Merit Bipolar Coagulation Probe
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: August 10, 2010
Received: August 11, 2010

Dear Mr. Lindsay:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4.0 Indications for Use Statement

510(k) Number (if known): K102273

SEP 07 2010

Device Name:

Indications for Use:

The Bipolar Coagulation Probe is intended to be passed through an endoscope's working channel to provide hemostasis throughout the gastrointestinal tract.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K102273