Medtronic

K140165

510(k) Summary

Date Prepared: January 17, 2014

MAY 20 2014

Submitter: Medtronic, Inc.
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7611 Northland Drive
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Establishment Registration Number: 2184009

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Device Name and Classification

Trade Name: MC2™ Two-Stage Venous Cannula
OVAL MC2™ Two-Stage Venous Cannula
Thin Wall Two-Stage Venous Cannula
MC2X™ Three-Stage Venous Cannula

Common Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing

Regulation Number: 870.4210

Product Code: DWF

Product Classification: Class II

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Predicate Devices

K052372 MC2X™ Multi-Stage Venous Cannula
K120988 DLP™ Single Stage Venous Cannula

Device Description

The Multi-Stage Venous Cannula product family includes the MC2™ Two-Stage Venous Cannula, OVAL MC2™ Two-Stage Venous Cannula, Thin Wall Two-Stage Venous Cannula, and MC2X™ Three-Stage Venous Cannula configurations. All Multi-Stage Venous Cannula configurations feature a wire wound polyvinyl chloride (PVC) body with side ports in the distal tip, a ported atrial basket, and a ⅜ inch (0.95cm) – ½ inch (1.27cm) connection site. The overall length of each cannula is approximately 15¼ inch (38.7cm). Insertion depth marks are provided to aid in positioning of the cannula during the surgical procedure. These cannulae are sterile, non-pyrogenic, disposable medical devices.

Indications for Use

This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.

Comparison to Predicate Devices

A comparison of the modified Multi-Stage Venous Cannula product to the currently marketed predicate products (K052372 and K120988) indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials (Polyvinyl Chloride (PVC), Stainless Steel)
- Same shelf life

Summary of Performance and Biological Testing

Medtronic conducted the following performance testing for the modified Multi-Stage Venous Cannula product:

- Kink / Bend
- Collapse under negative pressure
- Tensile strength / Pull

Additionally, biocompatibility testing was performed in accordance with EN ISO 10993-1 *Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process.* Performance and biological tests confirm that the modified Multi-Stage Venous Cannula product met pre-determined acceptance criteria and is substantially equivalent to the predicate device.

Conclusion

Medtronic has demonstrated that the modifications made to the Multi-Stage Venous Cannula product family described in this submission result in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 20, 2014

Medtronic, Inc.
Medtronic Perfusion Systems
Jacqueline A. Hauge
Senior Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, MN 55428

Re: K140165
Trade/Device Name: MC2™ Two-Stage Venous Cannula
OVAL MC2™ Two-Stage Venous Cannula
Thin Wall Two-Stage Venous Cannula
MC2X™ Three-Stage Venous Cannula

Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: February 17, 2014
Received: February 19, 2014

Dear Ms. Hauge:

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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 on last page.

510(k) Number *(if known)*

K140165

Device Name
MC2™ Two-Stage Venous Cannula

Indications for Use *(Describe)*

This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*