K132645

510(k) Summary

Date Prepared: August 21, 2013

Submitter:
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Establishment Registration Number: 2184009

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OCT 04 2013

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Device Name and Classification

Trade Name:	ThoraTrak™ MICS Retractor System
Common Name:	Retractor, Manual surgical instrument for general use
Regulation Number:	21 CFR 878.4800
Product Code:	GAD
Product Classification:	Class I

Predicate Devices

Legally Marketed Class I Retractor System	ThoraTrak™ MICS Retractor System

Device Description

The ThoraTrak™ minimally invasive cardiac surgery (MICS) retractor system is designed for use with a minimally invasive thoracotomy, an incision in the chest wall into the pleural space, for procedures that include Coronary Artery Bypass Grafting (CABG) and Left Internal Mammary Artery (LIMA) harvesting. It consists of a retractor rack, 2 sets of LIMA blades, 4 sets of thoracotomy blades, and 2 extended mount blades. The retractor rack and blades are chrome-coated stainless steel. They are non-sterile, nonpyrogenic, and reusable.

Indications for Use

The ThoraTrak™ minimally invasive cardiac surgery (MICS) retractor system is intended to provide surgical access for minimally invasive cardiothoracic procedures, including minimally invasive coronary artery bypass grafting (CABG) surgery and LIMA harvest, by retraction of soft and bony tissue.

Comparison to Predicate Devices

A comparison of the modified product to the currently marketed predicate products indicates the following similarities:

- Same intended use and target market
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials
- Same shelf life

Conclusion

Medtronic has demonstrated that the indications for use modification made to the ThoraTrak™ minimally invasive cardiac surgery (MICS) retractor system described in this submission results in a substantially equivalent device because the fundamental scientific principle, operating principle, design features, and overall intended use are unchanged from the predicate device.

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

October 4, 2013

Medtronic, Incorporated
Ms. Chelsea Pioske
Associate Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K132645
Trade/Device Name: ThoraTrak™ MICS Retractor System
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: GAD
Dated: August 21, 2013
Received: August 23, 2013

Dear Ms. Pioske:

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 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. 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known):

Device Name: ThoraTrak™ MICS Retractor System

Indications for Use:

The ThoraTrak™ minimally invasive cardiac surgery (MICS) retractor system is intended to provide surgical access for minimally invasive cardiothoracic procedures, including minimally invasive coronary artery bypass grafting (CABG) surgery and LIMA harvest, by retraction of soft and bony tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A [redacted] for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132645