K041338

JUL 1 9 2004

Confidential

510(k) Summary

Submitter: Medtronic Cardiac Surgery Technologies
7601 Northland Drive
Minneapolis, MN 55428

Contact: Scott Cundy

Telephone: (763) 391-9941
Fax: (763) 391-9279

Date Prepared: 18 May 2004

Trade Name: Medtronic Octopus® TE Stabilizer & Accessories

Common Name: Cardiovascular Surgical Instrument/Heart Stabilizer

Equivalence to: The Medtronic Octopus TE Stabilizer & Accessories are substantially equivalent in patient population, intended use, function and basic system components to the Medtronic Octopus Tissue Stabilizer (K964445) and the CTS (Guidant) Vacuum Assist Stabilizer (K992833).

The Medtronic Octopus TE Stabilizer has an optional irrigator (lavage) that is designed to provide drip irrigation for improved visibility. Said irrigator has a similar surgical site cleansing indication for use as existing jet lavage systems such as the Medtronic Clearview Blower/Misted (K973485).

Description: The non-sterile, reusable Medtronic Octopus TE Heart Stabilizing System is a suction-based tissue stabilizer with a collapsible pod assembly, a rigid shaft and 5 articulating links designed to enable transfer into the thoracic cavity via a 12 mm thoracic port or traditional sternotomy access. It is comprised of four distinct elements: (1) the Medtronic Octopus TE Tissue Stabilizer, (2) the Medtronic Octopus TE Suction Lines, (3) the Medtronic Octopus TE Vacuum Lines, and (4) the Medtronic Octopus TE Irrigator (optional).

The Medtronic Octopus TE Heart Stabilizer is secured to a flexible arm and universal mounting rail, which attached to the operating table rail. Vacuum is delivered to the pod assembly by a disposable suction line inserted through the shaft of the stabilizer and a disposable vacuum line that connects the stabilizer to the vacuum source. The accessories are sold separately.

Intended Use:	The Medtronic Octopus TE Stabilizer is used to stabilize the epicardial surface of the non-arrested heart during coronary artery surgery. It is intended to be used by trained medical professionals in operating room environments.
Technological Characteristics:	Comparisons between the new and predicate devices shows that technological characteristics (i.e. device design and principal of operation) are substantially equivalent.
Conclusion:	The Medtronic Octopus TE Stabilizer was found to be substantially equivalent in patient population, intended use, principal of operation and basic system components to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2004

Medtronic Cardiac Surgery Technologies
c/o Davis D. Cox, Ph.D.
Principal Regulatory Affairs Specialist
7601 Northland Drive
Minneapolis, MN 55428-1088

Re: K041338
Octopus TE Tissue Stabilizer
Regulation Number: 21 CFR 870.4500
Regulation Name: Cardiovascular Surgical Instruments
Regulatory Class: Class I (one)
Product Code: MWS
Dated: July 8, 2004
Received: July 9, 2004

Dear Dr. Cox:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K041338**

Device Name: **Octopus TE Tissue Stabilizer**

Indications for Use:

The Stabilizer is intended to stabilize the epicardial surface of the non-arrested heart during coronary artery surgery. It is intended to be used only by medical professionals in operating room environments.

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 THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

)ivision Sign-Off)
·ision of Cardiovascular Devices

·K) Number K041338