OCT 2 4 2001

K012143

APPENDIX III

SUMMARY OF SAFETY AND EFFECTIVENESS
TRUTHFUL AND ACCURATE STATEMENT
DECLARATION OF CONFORMITY

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY

Medtronic, Inc.
Medtronic Cardiac Surgical Products
620 Watson Street S.W.
Grand Rapids, MI 49504

CONTACT PERSON

Melissa Harriger
Associate Product Regulations Manager
Medtronic Cardiac Surgical Products
620 Watson Street SW
Tel: 616-643-5519
FAX: 616-643-1017

DEVICE NAME

24 Fr. Left Heart Vent Catheter w/ Pressure Monitoring Line (12524)

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

Adult Vent Catheter (K834352)
Aortic Root Cannula with Pressure Monitoring Line (K831591)

DESCRIPTION OF DEVICE

The 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line is designed for use in venting the left heart during cardiopulmonary bypass surgery.

The 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line is equipped with a pressure monitoring line, which allows measurement of left ventricular pressure.

STATEMENT OF INTENDED USE

The 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line is intended for use in venting the left heart during cardiopulmonary bypass surgery.

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The Adult Vent Catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"SPECIAL 510(k)"** is being submitted for a modification to the Adult Vent Catheter. The modification to the current Adult Vent Catheter is to include a pressure monitoring line and material change.

The 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line is being compared to the following Marketed Devices:

- Adult Vent Catheter (K834352)
- Infant Vent Catheter (K834039)
- Aortic Root cannula(s) with Integral Pressure Monitoring Line (K831591)

The 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line has the same indications statement and intended uses as the:

- Adult Vent Catheter (K834352)
- Infant Vent Catheter (K834039)

The 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line has no new technological characteristics (e.g. materials and manufacturing processes). The technological characteristic of the pressure monitoring line is common to other products in commercial distribution as follows. Additionally, using Polyvinyl Chloride (PVC) is common to other catheter products in distribution, as indicated below in the Infant Vent Catheter.

- Aortic Root Cannula with Integral Pressure Monitoring Line (K831591)
- Infant Vent Catheter (K834039)

This technological characteristic "could affect the safety and effectiveness of the device". However, this technological characteristic does not raise new types of safety or effectiveness questions. In addition, "there are acceptable scientific methods which exist for assessing effects of this technological characteristic".

"Performance data to assess the effects of this technological characteristic" has been performed. These "performance data demonstrate" that the 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line is substantially equivalent to other Medtronic marketed cannula.

The biocompatibility rationale and *in vitro* bench testing demonstrated that when compared to the predicate devices, the 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed devices. The *in vitro* bench testing included analysis of: kink testing, clamp testing, flexibility testing, burst, leak testing, pull testing and pressure monitoring capability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2001

Ms. Melissa Harriger
Associate Product Regulation Manager
Medronic Cardiac Surgery
620 Watson SW
Grand Rapids, MI 49504

Re: K012143
Trade Name: 24 Fr. Left Heart Vent Catheter w/ Pressure Monitoring Line
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Steerable
Regulatory Class: Class II (two)
Product Code: DRA
Dated: September 24, 2001
Received: September 25, 2001

Dear Ms. Harriger:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number if known: K012143

Device Name: 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line

Indications for Use:

The 24 Fr. Left Heart Vent Catheter with Pressure Monitoring Line is intended for venting the left heart during cardiopulmonary bypass surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter use

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012143