

SEP 12 2000

K991502

X. Safety and Effectiveness Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 882.5550

Establishment Registration Number: 2021898
Address of Manufacturer: Medtronic PS Medical Corporation
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 ext. 1770
Fax: (805) 968-5038

Contact Person: Jeffrey Henderson

Date: September 12, 2000

Trade or Proprietary Name: Medtronic PS Medical Polyurethane Shunt

Common usual or Classification Name: CSF-Flow Control Shunt (882.5550)

Description: A Ventricular Catheter manufactured of Polyurethane tubing. A Flow Control Valve manufactured of a Polypropylene base and a silicone elastomer housing which incorporates a Tecoflex elastomer resin, polyurethane coating. A Cardiac/Peritoneal Catheter manufactured of Polyurethane tubing.

Intended Use: The polyurethane-coated Delta Valves, polyurethane-coated CSF-Flow Control Valves, Contoured, and Burr Hole are components of polyurethane shunt systems designed for use in shunting cerebrospinal fluid from the ventricles of the brain into the right atrium of the heart or to the peritoneal cavity. The Polyurethane shunt and shunt components are designed to eliminate patient exposure to silicone elastomer.

The polyurethane-coated Delta Valve minimizes the excessive reduction of intraventricular pressure and volume due to excessive drainage of CSF, which may be caused by the siphoning effect of hydrostatic pressure of the distal catheter. The siphon effect may be created by the elevation of the ventricular catheter with respect to the distal catheter (i.e., when the patient sits, stands, or is held erect).

Technological comparison: Medtronic PS Medical submits that the materials of fabrication, intended uses, performance characteristics and design specifications of the Polyurethane Shunt are substantially equivalent to those of the predicate devices manufactured by Medtronic PS Medical and other currently marketed devices. Based upon the summary above, Medtronic PS Medical determines substantial equivalence, safety, and efficacy of the Polyurethane Shunt based upon the currently marketed devices.



SEP 12 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jeffrey Henderson
Vice President, Quality and
Regulatory Affairs
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117

Re: K991502
Trade Name: Medtronic PS Medical Polyurethane Shunt
Regulatory Class: II
Product Code: JXG
Dated: June 12, 2000
Received: June 14, 2000

Dear Mr. Henderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Jeffrey Henderson

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Polyurethane Shunt

510(k) Number (if known): K991502

Indications for Use:

The polyurethane-coated Delta Valves, polyurethane-coated CSF-Flow Control Valves, Contoured, and Burr Hole are components of polyurethane shunt systems designed for use in shunting cerebrospinal fluid from the ventricles of the brain into the right atrium of the heart or to the peritoneal cavity. The Polyurethane shunt and shunt components are designed to eliminate patient exposure to silicone elastomer.

The polyurethane-coated Delta Valve minimizes the excessive reduction of intraventricular pressure and volume due to excessive drainage of CSF, which may be caused by the siphoning effect of hydrostatic pressure of the distal catheter. The siphon effect may be created by the elevation of the ventricular catheter with respect to the distal catheter (i.e., when the patient sits, stands, or is held erect).

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

MRO for cmw
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K991502

Over the Counter Use:
or
Prescription Use:
(Per 21 CFR 801.109)

(optional format 1-2-96)