JUN 16 1998

X. Safety and Effectiveness Summary

K981046

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Establishment Registration Number:	2021898
Address of Manufacturer:	Medtronic PS Medical Corporation 125 Cremona Drive Goleta CA, 93117 (805) 968-1546 ext. 1776 Fax: (805) 968-5038
Contact Person:	Richard M. Ruedy
Date:	March 4, 1998
Trade or Proprietary Name:	Medtronic PS Medical External Drainage and Monitoring (EDM) Ventricular Catheter w/BioGlide
Common usual or Classification Name:	Ventricular Catheter (882.4100)

Predicate Device Identification: Codman External Drainage Catheter Set (K902257, K920938), Medtronic PS Medical Ventricular Catheter with BioGlide submitted under the Premarket Notification for the BioGlide Shunt Kit (K951258)

Description: The Medtronic PS Medical EDM Ventricular Catheter with BioGlide is manufactured of translucent silicone elastomer w/barium impregnated stripe. The catheter is provided in two sizes and incorporates a BioGlide surface modification on the interior and exterior of the catheter.

Intended Use: The Medtronic PS Medical EDM Ventricular Catheters with BioGlide are designed for use as the proximal component for cerebrospinal fluid (CSF) drainage and/or monitoring from the lateral ventricles of the brain.

Intended Use predicate device: "Use of the Codman External Drainage Catheter Set is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing and controlling increased intracranial volume and pressure when the insertion of a permanent internal shunt is not indicated."

Technological comparison: Medtronic PS Medical submits that the materials of fabrication, intended uses, performance characteristics and design specifications of the EDM Ventricular Catheter with BioGlide are substantially equivalent to those of the predicate devices. Based upon the summary above, Medtronic PS Medical determines substantial equivalence, safety, and efficacy of the

EDM Ventricular Catheter with BioGlide based upon the predicate and currently marketed devices.

Feature	Medtronic PS Medical EDM Catheter with BioGlide	Medtronic PS Medical Ventricular Catheter with BioGlide	Codman External Drainage Catheter Set
Materials	Silicone elastomer,	Silicone elastomer,	Silicone elastomer,
Dimensions	Diameter 1-3mm Length 20-40cm	Diameter 1-3mm Length 20-40cm	1-4mm
Sterility Method	EtO	EtO	not specified
Sterile	Sterile single use device	Sterile single use device	Sterile single use device
Intended Use	The device is indicated for use as the proximal component for draining and monitoring of CSF flow from the lateral ventricles of the brain.	The ventricular Catheter is designed for use as the proximal component of a CSF Flow Control Shunt 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 Codman External Drainage Catheter Set is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing and controlling increased intracranial volume and pressure when the insertion of a permanent internal shunt is not indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1998

Mr. Richard M. Ruedy
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117-5500

Re: K981046
Trade Name: Medtronic PS Medical External Drainage and Monitoring (EDM) Ventricular Catheter with BioGlide
Regulatory Class: II
Product Code: JXG
Dated: March 17, 1998
Received: March 20, 1998

Dear Mr. Ruedy:

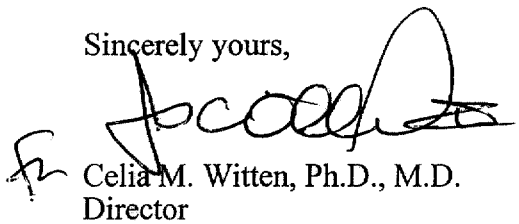
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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

Enclosure

Device Name: External Drainage and Monitoring (EDM) Ventricular Catheter with BioGlide

510(k) Number (if known): K981046

Indications for Use:

"The EDM Ventricular Catheters with BioGlide are designed for use as the proximal component for cerebrospinal fluid (CSF) drainage and/or monitoring from the lateral ventricles of the brain."

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981046

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

Prescription Use X
(Per 21 CFR 801.109)

(optional format 1-2-96)