DEC 16 1998

K983331

X. Safety and Effectiveness Summary

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. 1770 Fax: (805) 968-5038
Contact Person:	Jeffrey Henderson
Date:	August 17, 1998
Trade or Proprietary Name:	Medtronic PS Medical Innervision Ventricular Catheter w/BioGlide
Common usual or Classification Name:	Ventricular Catheter (882.4100)

Predicate Device Identification: Medtronic PS Medical Innervision Ventricular Catheter submitted under the Premarket Notification for the Catheter Placement Kit (K940096), Medtronic PS Medical Ventricular Catheter with BioGlide submitted under the Premarket Notification for the BioGlide Shunt Kit (K951258)

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

Intended Use: The Innervision Ventricular Catheter with BioGlide is designed to be used with the Neuropen endoscope or other compatible Medtronic PS Medical endoscope when the physician desires direct vision from the tip of a ventricular catheter during its placement. Direct vision facilitates placement of the catheter tip at a specific intraventricular location. The catheter is designed to be used 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.

Intended Use predicate device: The Innervision Ventricular Catheter is designed to be used with the Innervision endoscope when the physician desires direct vision from the tip of a ventricular catheter during its placement. Direct vision facilitates placement of the catheter tip at a specific intraventricular location. The catheter is designed to be used 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.

Technological comparison: Medtronic PS Medical submits that the materials of fabrication, intended uses, performance characteristics and design specifications of the Innervision 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 Innervision Ventricular Catheter with BioGlide based upon the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1998

Mr. Jeffrey Henderson
Vice-President, Quality
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117-5500

Re: K983331
Trade Name: Medtronic PS Medical Innervision Ventricular Catheter With Bioglide
Regulatory Class: II
Product Code: HCA
Dated: September 18, 1998
Received: September 22, 1998

Dear Mr. Henderson:

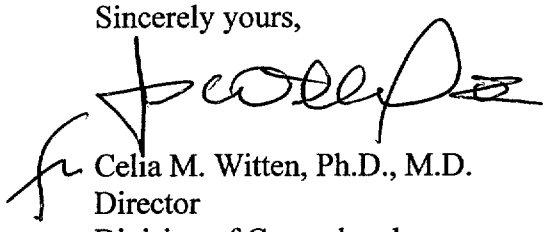
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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: Innervision Ventricular Catheter with BioGlide

510(k) Number (if known): K983331

Indications for Use:

"The Innervision Ventricular Catheter with BioGlide is designed to be used with the Neuropen endoscope or other compatible Medtronic PS Medical endoscope when the physician desires direct vision from the tip of a ventricular catheter during its placement. Direct vision facilitates placement of the catheter tip at a specific intraventricular location. The catheter is designed to be used 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."

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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

(optional format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983331