4/28/99

K990333

X. Safety and Effectiveness Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 882.4545

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:	Jeffrey Henderson
Date:	January 29, 1998
Trade or Proprietary Name:	Medtronic PS Medical Endoscope Introducer
Common usual or Classification Name:	Instrument, Shunt System (882.4545)
Predicate Device Identification:	Neuro Navigational Peel Away Introducer Sheath (K931973) Codman Peel Away Sheath (K883607)

Description: The Introducer Sheath includes two parts, a peelaway sheath and a blunt ended obturator, which fits inside the sheath. The Introducer Sheath provides an atraumatic passage into the ventricular system.

Intended Use: The Introducer Sheath is a device used to make a channel through the brain into the ventricular system

Intended Use predicate device: The Disposable Neuroview Endoscope is intended for use in direct visualization, diagnosis of disease and therapeutic applications for intracranial procedures (e.g., biopsy, tumor resection, coagulation of choroid plexus, cyst fenestration, shunt placement, etc.).

Technological comparison: Medtronic PS Medical submits that the materials of fabrication, intended uses, performance characteristics and design specifications of the Endoscope Introducer 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 Endoscope Introducer based upon the predicate and currently marketed devices.

Feature	Medtronic PS Medical Endoscope Introducer	Neuro Navigational Peel Away Introducer Sheath	Codman Peel Away Sheath
Device configuration/ contents	• Peel Away Sheath • Obturator	• Peel Away Sheath • Obturator	• Peel Away Sheath • Obturator
Sterility Method	EtO	not specified	not specified
Sterile	Sterile single use device	Sterile device single use	Sterile single use device
Intended Use	The Introducer Sheath is a device used to make a channel through the brain into the ventricular system.	The Disposable Neuroview Endoscope is intended for use in direct visualization, diagnosis of disease and therapeutic applications for intracranial procedures (e.g., biopsy, tumor resection, coagulation of choroid plexus, cyst fenestration, shunt placement, etc.).	not specified

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1999

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

Re: K990333
Trade Name: Endoscope Introducer
Regulatory Class: II
Product Code: GWG
Dated: January 29, 1999
Received: February 3, 1999

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: Endoscope Introducer 510(k) Number (if known): K990333

Indications for Use:

The Introducer Sheath is a device used to make a channel through the brain into the ventricular system.

(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 K990333

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

(optional format 1-2-96)

Prescription Use X
(Per 21 CFR 801.109)