JAN 26 1999

K983799

X. Safety and Effectiveness Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 882.1620

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:	July 20, 1998
Trade or Proprietary Name:	Medtronic PS Medical Niveau Drainage System
Common usual or Classification Name:	Intracranial Pressure Monitoring Devices (882.1620)
Predicate Device Identification:	Codman External Drainage System (K954021), Clinical Neuro Systems MoniTorr (K920156)

Description: The reusable portion of the system is comprised of a pressure scale, mounting clamp and optional laser level. All components of the reusable device are integrated during manufacture. The scale has a blue anodized finish with contrasting pressure scale. Down the center of the scale is a track for the disposable device to be retained. The scale is integrated into a pole clamp that has been ergonomically designed to facilitate use. An optional laser device may be attached to the pole clamp. It is used to obtain a zero pressure reference with the patients Foramen of Monro.

The disposable device is comprised of three basic elements: a patient line that is attached to an externalized CSF drainage catheter, graduated drip chamber, and drainage bag. The drip chamber has an integrated mounting bracket that is inserted into the track on the reusable scale.

Intended Use: "Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to

1. Reduce intracranial pressure (ICP), e.g. pre-intra- or postoperative;
2. Monitor CSF chemistry, cytology and physiology;
3. Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

The monitoring of the intracranial pressure (ICP) is indicated in selected patients with

1. Severe head injury;

2. Subarachnoid hemorrhage graded III, IV or V preoperatively;
3. Reyes syndrome or similar encephalopathies;
4. Hydrocephalus;
5. Intracranial hemorrhage
6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver. Monitoring can also be used to evaluate the status pre-and postoperatively for space occupying lesions."

Intended Use predicate device: "The MoniTorr system allows for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and the monitoring of ICP."

"Use of the Codman External Drainage System II 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 Niveau Drainage System 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 Niveau Drainage System based upon the predicate and currently marketed devices.

Feature	Medtronic PS Medical Niveau Drainage System	Clinical Neuro Systems MoniTorr	Codman External Drainage System II
Device configuration/ contents	• Locking bracket integral with mounting panel • Mounting panel main system section with pressure scale in mmHg and cmH_20 • 50 cc Conical sliding graduated flow chamber with locking bracket and vent system • Nondistensible blue striped patient connection line • Two four way stopcocks • One non-latex injection/sampling sites • 500 - 800 ml drainage bag (removable) with volumetric graduations, microbial filter and drain port • Drainage bag connection line • Laser leveling device	• Pole mount bracket assembly, braided cord and cord lock • System Panel with instruction label • 100 ml graduated chamber with filter vent • Nondistensible green striped patient connection line • Two four way stopcocks • Two injection sites • 500ml drainage bag with valve and drain port • Line level	• Doubled 24 in. string w/Cord-loc® locking mechanism • 27 cm measuring backboard • 75 ml drip chamber with anti-reflux valve and atmospheric vent • 157 cm patient line with two slide clamps • Two four way stopcocks with female luer port • Two latex injection/sampling sites • 700 ml capacity graduated vinyl collection bag

Feature	Medtronic PS Medical Niveau Drainage System	Clinical Neuro Systems MoniTorr	Codman External Drainage System II
Sterility Method	EtO	EtO	not specified
Sterile	Sterile device with reusable mounting panel section and disposable fluid contact section	Sterile device with reusable mounting panel section and disposable fluid contact section	Sterile single use device
Intended Use	"Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to Reduce intracranial pressure (ICP), e.g. pre-intra- or postoperative; Monitor CSF chemistry, cytology and physiology; Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts. The monitoring of the intracranial pressure (ICP) is indicated in selected patients with Severe head injury; Subarachnoid hemorrhage graded III, IV or V preoperatively; Reyes syndrome or similar encephalopathies; Hydrocephalus; Intracranial hemorrhage Miscellaneous problems when drainage is to be used as a therapeutic maneuver. Monitoring can also be used to evaluate the status pre-and postoperatively for space occupying lesions."	"The MoniTorr system allows for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and the monitoring of ICP."	"Use of the Codman External Drainage System II 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

JAN 26 1999

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

Re: K983799
Trade Name: Medtronic PS Medical Niveau Drainage System
Regulatory Class: II
Product Code: JXG and GWM
Dated: October 23, 1998
Received: October 28, 1998

Dear Mr. Henderson:

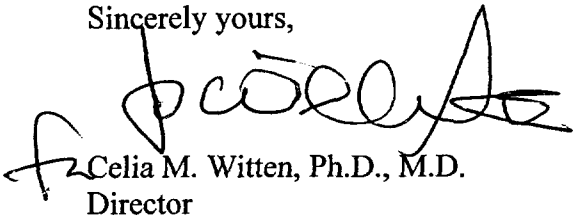
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known):

Indications for Use:

"Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to

1. Reduce intracranial pressure (ICP), e.g. pre-intra- or postoperative;
2. Monitor CSF chemistry, cytology and physiology;
3. Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

The monitoring of the intracranial pressure (ICP) is indicated in selected patients with

1. Severe head injury;
2. Subarachnoid hemorrhage graded III, IV or V preoperatively;
3. Reyes syndrome or similar encephalopathies;
4. Hydrocephalus;
5. Intracranial hemorrhage
6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver. Monitoring can also be used to evaluate the status pre-and postoperatively for space occupying lesions."

(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 K983799

[redacted]

Prescription Use:
(Per 21 CFR 801.109) X

(optional format 1-2-96)