7. 510(k) Summary

SEP – 2 2009

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 Neurosurgery 125 Cremona Drive Goleta, CA 93117 USA (805) 571-8445 Fax: (805) 571-8480
Contact Person:	Jeffrey Henderson
Date:	April 30, 2009
Trade or Proprietary Name:	PS Medical® Strata® NSC Lumboperitoneal Valve and Shunt System
Common Name:	Central Nervous System Flow Control Shunts and Accessories
Classification Name:	Shunt, Central Nervous System and Components (21 CFR 882.5550, Product Code JXG)
Predicate Device Identification:	• PS Medical® Strata® NSC Valve and Shunt Assemblies with and without BioGlide (K033850) • CSF-Lumboperitoneal Shunt System (K831396)

Device Description

PS Medical® Strata® NSC Lumboperitoneal Valve and Shunt System are designed for diversion of cerebrospinal fluid (CSF) from the lumbar subarachnoid space into the peritoneal cavity.

The shunt's implantable components include:

- Strata NSC Lumboperitoneal Valve
- Lumbar Catheter, Closed Tip, Barium Impregnated
- Lumbar Catheter, Open Tip, Barium Impregnated
- Peritoneal Catheter, Small Lumen, Open End, Barium Impregnated
- Strain Relief
- Fixation Tabs

Intended Use

The Strata NSC Lumboperitoneal (LP) Valve and Shunt System are designed for the management of communicating hydrocephalus, including normal pressure hydrocephalus (NPH), and idiopathic intracranial hypertension (IIH), also known as pseudotumor cerebri.

Indications for Use

The Strata NSC Lumboperitoneal Shunt System provides continued cerebrospinal fluid (CSF) flow from the subarachnoid space into the peritoneal cavity. The Strata NSC Lumboperitoneal Valve allows the physician to non-invasively adjust the pressure/flow performance level pre- and post-implantation without the need for radiographic confirmation in order to address changing patient needs. The Strata NSC Lumboperitoneal Shunt System is designed for management of communicating hydrocephalus.

Technological Comparison and Performance Characteristics

The predicate Strata NSC Valve was cleared in April 2004 (K033850) and was developed to serve those patients who needed an adjustable valve technology but without the siphon control feature. The predicate CSF-Lumboperitoneal Shunt was cleared in August 1983 (K831396). The Strata NSC LP Valve and Shunt System utilize the same fundamental scientific technology, materials, and sterilization method as the predicates. The device combines the Strata-type adjustable technology with geometrical shunt features that are tailored for use in the lumboperitoneal configuration (shunting from the intrathecal space of the spine to the peritoneal cavity).

Test Data

Testing performed on the Strata NSC LP Valve and Shunt System verified that the system met the required specifications and acceptance criteria.

Summary

Based upon the product technical information, intended use, and test data, the Strata NSC LP Valve and Shunt System have been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Medtronic Neurosurgery
c/o Jeffrey Henderson
Vice President, Quality & Regulatory Affairs
125 Cremona Drive
Goleta, CA 93117-5500

SEP – 2 2009

Re: K091312
Trade Name: PS Medical® Strata® NSC Lumboperitoneal Valve and Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: July 20, 2009
Received: August 4, 2009

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Teresa Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number (if known): K091312

Device Name: PS Medical® Strata® NSC Lumboperitoneal Valve and Shunt System

Indications for Use:

The Strata NSC Lumboperitoneal Shunt System provides continued cerebrospinal fluid (CSF) flow from the subarachnoid space into the peritoneal cavity. The Strata NSC Lumboperitoneal Valve allows the physician to non-invasively adjust the pressure/flow performance level pre- and post-implantation without the need for radiographic confirmation in order to address changing patient needs. The Strata NSC Lumboperitoneal Shunt System is designed for management of communicating hydrocephalus.

Prescription Use (Part 21 CFR CFR 801	✓	AND/OR 801 Subpart D) Subpart C)	Over-The-Counter Use	(21

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091312