

4. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number: 2021898

Address of Manufacturer: Medtronic Neurosurgery  
125 Cremona Drive  
Goleta CA, 93117  
(805) 571-8445  
Fax: (805) 571-8480

Contact Person: Jeffrey Henderson

Date: October 14, 2008

Trade or Proprietary Name: PS Medical® Strata® Burr Hole Valves and Shunt Assemblies

Common Usual or Classification Name: Central nervous system fluid shunt and components (882.5550)

Predicate Device Identification:

- Medtronic PS Medical Strata II Valves and Shunt Assemblies with and without BioGlide (K042465)
- PS Medical Strata NSC Burr Hole Valves and Shunt Assemblies (K082127)

Description:

The PS Medical® Strata® Burr Hole Valve is an adjustable valve designed for non-invasive pressure flow adjustment.

Intended Use:

- The Strata Burr Hole Valves and Shunt Assemblies are shunt components designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata Burr Hole Valve allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation in order to address changing patient needs.

Intended Use of Predicate Device(s):

- The Strata II Valves and Shunt Assemblies are shunt components designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata II Valve

allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation in order to address changing patient needs.

- The Strata NSC Burr Hole Valves and Shunt Assemblies are shunt components designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata NSC Burr Hole Valve allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation in order to address changing patient needs.

Technological Comparison:

Medtronic Neurosurgery submits that the Strata Burr Hole Valves and Shunt Assemblies included in this submission are manufactured of **identical** materials, and have the same intended use and fundamental scientific technology as the previously reviewed and cleared:

- Medtronic PS Medical Strata II Valves and Shunt Assemblies with and without BioGlide (K042465)
- PS Medical Strata NSC Burr Hole Valves and Shunt Assemblies (K082127).

Based upon the summary above, Medtronic Neurosurgery has determined that the proposed Strata Burr Hole Valves and Shunt Assemblies are safe and effective and substantially equivalent to the predicate and currently marketed devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medtronic Neurosurgery  
% Mr. Jeffrey Henderson  
VP, Quality and Regulatory Affairs  
125 Cremona Drive  
Goleta, California 93117

NOV 20 2008

Re: K083076

Trade/Device Name: PS Medical® Strata® Burr Hole Valves and Shunt Assemblies  
Regulation Number: 21 CFR 882.5550  
Regulation Name: Central nervous system fluid shunt and components  
Regulatory Class: II  
Product Code: JXG  
Dated: October 15, 2008  
Received: October 21, 2008

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 such 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); 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.

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This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K083076

Device Name: PS Medical® Strata® Burr Hole Valves and Shunt Assemblies

Indications for Use:

The Strata Burr Hole valve is a shunt component designed to provide continued cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata Burr Hole 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Neil R. Glick for man*

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K083076