JAN 2 8 2005

K041992

## IX. SAFETY AND EFFECTIVENESS SUMMARY
## Medtronic StrataVarius

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

**Establishment Registration Numer:** 2021898

**Address of Manufacturer:** Medtronic Neurosurgery
125 Cremona Drive
Goleta, CA 93117
(805) 968-1546

**Contact Person:** Jeffrey Henderson

**Date:** January 26, 2005

**Trade or Proprietary Name:** Medtronic StrataVarius™

**Common, Usual or Classification Name:** CSF Flow control Shunts and Accessories (21 CFR 882.5550)

**Predicate Device Identification:** Medtronic Strata Adjustment Kit (K012052, K040943)

**Device Description:**
Medtronic Neurosurgery's StrataVarius™ System is a battery-powered, handheld instrument that senses the location and orientation of the magnet contained in PS Medical ® Strata-type adjustable valves. The StrataVarius™ works in conjunction with the StrataVarius Adjustment Tool to change the magnet orientation, and thus the valve Performance Level (PL) setting as determined by the clinician. The complete system includes the StrataVarius system includes the StrataVarius, an Adjustment Tool, two (or more) Valve Identification Cards (Smart Cards), a storage/carrying case, Instructions for Use, X-Ray Templates, and two 1.5 volt (AA) alkaline batteries.

**Intended Use:**
StrataVarius is intended for use by physicians, to non-invasively identify the Strata-type valve Performance Level (PL) setting and display that information numerically in terms of PL level and the equivalent pressure reading in millimeters of water (mm H2O). The StrataVarius allows the user to change the pressure setting of the valve non-invasively without the need for radiographic confirmation.

**Intended Use of Predicate Device:**
The Adjustment tool allows the user to change the pressure setting of the valve non-invasively.

**Technological Comparison:**
The StrataVarius is equivalent to the Strata Adjustment Kit (K012052, K040943). Substantial equivalence is based upon materials, design, performance specifications and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

Mr. Jeffrey Henderson
Vice President Quality &
Regulatory Affairs
Medtronic Neurosurgery
125 Cremona Drive
Goleta, California 93117-5500

Re: K041992
Trade/Device Name: Medtronic StrataVarius™
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: January 20, 2005
Received: January 21, 2005

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.

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K041992

Device Name: Medtronic StrataVarius™

Indications For Use:

"StrataVarius is intended for use by physicians, to non-invasively identify the Strata-type valve Performance Level (PL) setting and display that information numerically in terms of PL level and the equivalent pressure reading in millimeters of water (mm H2O). The StrataVarius allows the user to change the pressure setting of the valve non-invasively without the need for radiographic confirmation."

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K041992