4. 510(k) Summary

DEC 16 2005

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) 968-1546 ext. 1773 Fax: (805) 968-9336
Contact Person:	Jeffrey Henderson
Date:	August 25, 2005
Trade or Proprietary Name:	Medtronic M2 Magnet Adjustment Tool
Common usual or Classification Name:	Central Nervous System Flow Control Shunts and Accessories (882.5550)
Predicate Device Identification:	Adjustment tools for Medtronic PS Medical® Strata® Valve and Shunt Assemblies (K012052, K033850, and K042465)

Description: The Medtronic M2 Adjustment Tool is a magnetic tool that is used to non-invasively adjust the Strata-type Valve when a stronger magnet is warranted by the surgeon. External adjustment of the valve prevents the need for an invasive revision procedure. To adjust the operating pressure of the valve, the adjustment tool is used in close proximity to the valve to move the rotor within the valve.

Intended Use: The Medtronic M2 Adjustment Tool is a magnetic tool that is used to non-invasively adjust the Strata-type Valve when a stronger magnet is warranted by the surgeon. The Medtronic M2 Adjustment Tool is used in conjunction with Strata® handtools.

Intended Use of predicate device(s): The adjustment tools for the PS Medical Strata Valve and shunt component are used to non-invasively change the performance level (pressure/flow characteristics) of the Strata type valve.

Technological comparison: Medtronic Neurosurgery submits that the materials of fabrication, intended use, and the fundamental scientific technology of the M2

Magnet Adjustment Tool are the same as the previously reviewed and cleared adjustment tools for the Strata Valve and Shunt Assemblies. Based upon the summary above, Medtronic Neurosurgery determines substantial equivalence, safety, and efficacy of the adjustment tool products compared to the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. Jeffery Henderson
Vice President, Quality & Regulatory Affairs
Medtronic Neurosurgery
125 Cremona Drive
Goleta, California 93117-5000

Re: K052386
Trade/Device Name: Medtronic M2 Magnet Adjustment Tool
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: October 20, 2005
Received: October 24, 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,

Barbara Melkerup for

Mark N. Melkerson
Acting 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): K052386

Device Name: Medtronic M2 Adjustment Tool

Indications for Use:

The Medtronic M2 Adjustment Tool is a magnetic tool that is used to non-invasively adjust the Strata-type Valve when a stronger magnet is warranted by the surgeon. The Medtronic M2 Adjustment Tool is used in conjunction with Strata® handtools.

Prescription Use X 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)

Barbara Buchman for MKM

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

510(k) Number K052386