FEB 4 1999

II. Safety and Effectiveness Summary

K984053

Determination of substantial equivalence
The ICP monitoring device and method were first described in an article published in 1973. Over the years the device has come into widespread use.

Medtronic PS Medical has, with input from neurosurgeons, developed a device design, which is considered to be equivalent to the predicate Codman External Drainage System II (K902257, ~~K920938~~). The Medtronic PS Medical Becker EDMS is a complete closed system indicated for the draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space.

K910938 - listed incorrectly throughout

Medtronic PS Medical considers the Medtronic PS Medical Becker EDMS to be substantially equivalent to the Codman External Drainage System II (K902257, K920938), currently in commercial distribution. The predicate device is used 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 needed. A comparison of the Codman External Drainage System II and the Medtronic PS Medical Becker EDMS is included in Tables 1 and 2.

Medtronic PS Medical considers the Becker EDMS to be safe, effective and substantially equivalent in indications, physical characteristics and performance to the noted predicate device. Evidence of this is provided in predicate device product labeling (Attachment 2).

Device Name
Medtronic PS Medical Becker External Drainage and Monitoring System (Becker EDMS).

Predicate Device(s)
Codman External Drainage System II (K902257, K920938)

Device Description
The Medtronic PS Medical Becker EDMS is indicated for the draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space. The Becker EDMS is substantially equivalent in indications, materials of fabrication, performance characteristics and design specifications as compared with the predicate device, Codman External Drainage System II.

The materials utilized in the Becker EDMS are not substantially different to those used in currently marketed products. The Becker EDMS is comprised of a nondistensible blue striped (proximal end) patient connection line, patient line stopcock, mounting panel/main system section, three non-latex injection sites, and a removable drainage bag with approximate volumetric graduations and microbial filter. A graduated 50 cc

flow chamber with drip former and conical bottom and locking bracket is included on the main system section.

A comparison of the Becker EDMS and predicate device is provided in Table 1.

Intended Use
The Medtronic PS Medical Becker EDMS will be indicated for use as follows:
"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 or 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."

Draft Medtronic PS Medical product labeling and product literature for the Medtronic PS Medical Becker EDMS is included (Attachment 1).

Intended Use predicate device
The predicate device Codman External Drainage System II is indicated for use as follows:

"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."

Product literature for the predicate Codman External Drainage System II is included (Attachment 2).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 1999

Mr. Jeffrey Henderson
Vice President, Quality
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117-5500

Re: K984053
Becker External Drainage and Monitoring System
Regulatory Class: II
Product Code: JXG
Dated: November 3 1998
Received: November 6, 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,

for 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: Becker External Drainage and Monitoring System (EDMS)

510(k) Number (if known): K984053

Indications for 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 or 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)

Nancy Pomeranz for JZP

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K984053

Over the Counter Use:
or
Prescription Use:
(Per 21 CFR 801.109)

(optional format 1-2-96)