K042359 1/3

NOV 17 2004

510(k) Summary

1. **Submitter Information:**

Medical Designs, LLC
NORTH CENTER, Suite 104
1210 W. 18th Street
Sioux Falls, South Dakota 57104
(605) 376-6008
(605) 335-3734 Fax
e-mail: paxt@medicaldesignsllc.com

Contact: Mr. Paul John Axt
Preparation Date: August 27, 2004

2. **Trade Name**:
Subdural Evacuating Port System Cranial Access Kit (SEPS Cranial Access Kit)

Common Name:
Subdural Fluid Drainage Kit

Classification Name:
Central Nervous System Fluid Shunts and Components
Regulation Number: 21 CFR 882.5550
Product Code: JXG

Classification:
The Subdural Evacuating Port System Cranial Access Kit is a Class II device. The Subdural Evacuating Port System Cranial Access kit includes Class II devices covered under Regulations: 21 CFR 882.5550, 21 CFR 882.4300, 21 CFR 880.5860, 21 CFR 880.5570, 21 CFR 878.5020, 21 CFR 878.4370, and Class I devices covered under Regulations: 21 CFR 880.5240, 21 CFR 878.4800, 21 CFR 878.4680, and 21 CFR 878.4014.

3. **Predicate Devices**:
   1. Subdural Evacuating Port System Kit, Medical Designs, LLC, Catalog # 11-9901 (# K002970).
   2. Ventriculostomy Kit, Medtronic Neurosurgery, Catalog # 46156, (#K915546).
   3. Ventriculostomy Kit, Medtronic Neurosurgery, Catalog # 46154, (#K915546).
   4. Cranial Access Kit, Integra NeuroSciences, Catalog # INS-HITH .

4. **Performance Standards**:
No applicable performance standards have been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act for this device.

5. **Device Description**:
The Subdural Evacuating Port System Cranial Access Kit is indicated when access to the subdural space and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The Subdural Evacuating Port System Cranial Access Kit consists of surgical instruments and accessories used for draining subdural fluid accumulations such as hygromas and liquid-state subdural hematomas to an external suction reservoir without touching the brain. Utilizing a minimally invasive technique, the Subdural Evacuating Port System Cranial Access Kit's **"SEPS Components"** are designed to promote gradual brain re-expansion by creating a low homogeneous negative pressure throughout the subdural space as fluid is drained to an external suction reservoir. The completeness of the Subdural Evacuating Port System Cranial Access Kit saves time and eliminates the need to gather supplies; this convenience can be critical in an emergency situation.

The Subdural Evacuating Port System Cranial Access Kit is available in three (3) kit configurations:

1. SEPS-CA, Catalog # 11-0401-CA (Standard Kit)
2. SEPS-CAL, Catalog # 11-0401-CAL (Standard Kit with Lidocaine w/epinephrine)
3. SEPS-CAND, Catalog # 11-0401-CAND (Standard Kit without Lidocaine, ChloraPrep® One-Step, or PVP (Povidone-Iodine) ointment – no drugs).

6. **Intended Use**:
"Use of the Subdural Evacuating Port System Cranial Access Kit is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The Subdural Evacuating Port System Cranial Access Kit is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The Subdural Evacuating Port System Cranial Access Kit is also intended for draining air and fluids from the subdural space immediately following craniotomy procedures performed to remove a chronic or subacute subdural hematoma."

"The Subdural Evacuating Port System Cranial Access kit is contraindicated for patients with acute subdural hematomas, patients undergoing anticoagulant therapy, and is not designed, sold, or intended for use except as indicated."

7. **Biocompatibility**:
The surgical instruments and accessories included in the Subdural Evacuating Port System Cranial Access Kit have been approved by the United States Food and Drug Administration, or are substantially equivalent to instruments and accessories approved by the United States Food and Drug Administration for use in neurosurgical procedures.
(Predicate Device # 1: Subdural Evacuating Port System Kit, Medical Designs, LLC, Catalog # 11-9901 (K002970); Predicate Device # 2: Ventriculostomy Kit, Medtronic Neurosurgery, Catalog # 46156 (K915546); Predicate Device # 3: Ventriculostomy Kit, Medtronic Neurosurgery, Catalog # 46154 (K915546), and; Predicate Device # 4: Cranial Access Kit, Integra NeuroSciences, Catalog # INS-HITH (510(k) # unknown)

8. **Summary of Substantial Equivalence**:
The Subdural Evacuating Port System Cranial Access Kit is substantially equivalent in part or in whole to one or more of the predicate devices in terms of intended use, materials, biocompatibility, design, performance, function and operating characteristics, and does not raise any new issues relating to the safety or effectiveness of its intended use.

9. **Performance Testing**:
The Subdural Evacuating Port System Cranial Access Kit is substantially equivalent to the Subdural Evacuating Port System Kit (Predicate Device #1) based on the successful performance testing and clinical data presented and accepted for the predicate device (510(k) # K002970).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Mr. Paul John Axt
Vice President of Operations
Medical Designs, LLC
North Center, Suite 104
1210 W. 18th Street
Sioux Falls, South Dakota 57104

Re: K042359
Subdural Evacuating Port System Cranial Access Kit (SEPS) Cranial Access Kit)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: October 11, 2004
Received: October 13, 2004

Dear Mr. Axt:

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 to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your product contains the following component(s) subject to regulation as drugs:

- ChloraPrep One Step 10.5ml Applicator,
- Povidone-Iodine Ointment (1.5gm),
- Lidocaine w/Epinephrine (30ml).

Our substantially equivalent determination does not apply to the drug component(s) of your product. For information on applicable Agency requirements for marketing this product, we suggest you contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 (21 CFR Part 807); 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 (Section 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 although we recommend that you first contact the Center for Drug Evaluation and Research before marketing your drug component[s]. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K042359

Device Name: Subdural Evacuating Port System Cranial Access Kit

Indications For Use:

"Use of the Subdural Evacuating Port System Cranial Access Kit is indicated when access to and evacuation of a cranial subacute or chronic hematoma or hygroma is necessary. The Subdural Evacuating Port System Cranial Access Kit is intended for drainage of subdural fluid accumulations such as hygromas and chronic or subacute hematomas to an external suction reservoir. The Subdural Evacuating Port System Cranial Access Kit is also intended for draining air and fluids from the subdural space immediately following craniotomy procedures performed to remove a chronic or subacute subdural hematoma."

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

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