K973277

NOV 17 1997

Surgical Solutions Inc.
2550 Bluffwood Circle
Iowa City, Iowa
USA
(319) 337-6882

# 510(k) Summary

(as required by section 807.92c)

**Submitters name, address, phone and fax:**

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2550 Bluffwood Circ.
Iowa City, IA 52245
phone: 319 337-6882
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**Name of contact person:**

Matthew A. Howard III, MD
President and CEO

**Date of summary preperation:**

September 1, 1997

**Proprietary name:**

Caroline Guide and Delia Localizer (to be sold together as an integrated system)

**Common name:**

Posterior Ventricular Catheter Guide (Caroline Guide) and Posterior Burr Hole Localizer (Delia Localizer)

**Classification name:**

Accessories to shunt system implantaton instruments, regulation number 21 CFR 882.4545 (per FDA correspondance, see Appendix D)

**Legally marketed device to which equivalence is being claimed:**

Ventricular catheter stylette (pre-amendment device)

**Discription of the device:**

The Delia Localizer is a head-band based apparatus that aids the surgeon in identifying the optimal location for placing a posterior burr hole for purposes of inserting a posterior ventricular catheter. It mechanically reduces to practice geometric principles that are already used to manually calculate where to position a posterior burr hole.

The Caroline Guide is a mechanical device that helps the surgeon orient a ventricular catheter along a straight line connecting the posterior burr hole entrance point and the frontal target point.

**The intended use:**

The Delia Localizer and Caroline Guide are intended to be used as an integrated system by neurosurgeons during posterior ventricular catheter placement procedures.

**Summary of the technological characteristics of the new device compared to the predicate device:**

The Delia Localizer and Caroline Guide integrated system have the following characteristics in common with the predicate device (catheter stylette)

1) same indications for use
2) same method for advancing the catheter into the ventricle
3) same materials exposure to the patient during surgery.

The Delia Localizer makes use of intersecting sighting devices to simplify a commonly used manual measuring technique and indicate where to locate a posterior burr hole. Surgeons using the predicate device and standard catheter placement techniques rely on manual measurements made along the scalp relative to palpable skull anatomic landmarks.

The Caroline Guide mechanically orients a catheter along a trajectory line between the posterior burr hole entrance point and the frontal target point. Surgeons using the predicate device and standard catheter placement techniques mentally visualize the intended catheter trajectory, orient the sylette by hand without mechanical assistance, and then manually advance the catheter towards the target.

**Discription of non-clinical tests:**

Pre-clinical testing was carried out to confirm the validity of the geometric principles embodied in the Delia Localizer for shunt surgery patients. This involved the antomical analysis of head CT scans of patients with hydrocephalus. Additionally, the Delia Localizer was tested on cranial phantoms of differing head sizes to ensure that device accurately reduced the geometric principles to practice.

The mechanical accuracy of the Caroline Guide was tested in non-clinical studies by passing ventricular catheters through the guide tube and confirming that the catheters maintain alignment with the frontal target point as they were advanced by hand.

**Discussion of clinical tests:**

The Caroline Guide was tested in a clinical trial at the Universities of Iowa and Washington. The trial were reported in the peer reviewed scientific literature (Appendix B) in 1995 and the device has been in routine clinical use at these two institutions since that time.

More recently, a clinical trial of the Delia Localizer in combination with Caroline Guide system was approved by the University of Iowa Institutional Review Board and clinical data is now available on clinical performance of the combined system.

**Conclusions drawn from the nonclinical and clinical tests:**

These pre-clinical and clinical test data indicate that the new technologic features of the Delia Localizer and Caroline Guide do not adversely affect safety or effetiveness in a way that is consequential under the conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Matthew A. Howard III, MD
President and CEO
Surgical Solutions, Inc.
2550 Bluffwood Circle
Iowa City, Iowa 52245

NOV 17 1997

Re: K973277
Trade Name: The Caroline Guide and Delia Localizer
Regulatory Class: II
Product Code: HAW
Dated: August 28, 1997
Received: September 2, 1997

Dear Dr. Howard:

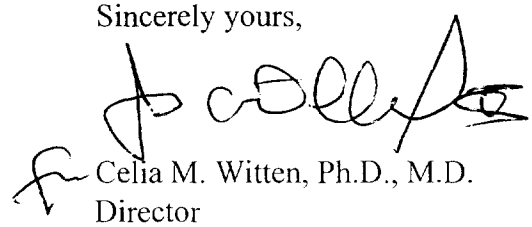
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 requirements , 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4648. Additionally, for questions on the promotion and advertising of your devices, 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,



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

(ADDITIONAL INFORMATION)

510(k) Number (if known): K973277

Device Name: Caroline Guide/Delia Localizer

Indications For Use:

## Statement of indications for use:

The Delia Localizer and Caroline Guide are indicated for use by neurosurgeons as shunt accessories for patients scheduled to undergo a posterior ventricular catheter placement procedure who are:

1) Adults
2) Have enlarged ventricles
3) Have normal scalp, skull, external ear and orbital anatomy
4) Do not have intracranial mass lesions or any structural abnormalities other than hydrocephalus
5) Have no general contraindications to surgery

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973277

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)