AUG 14 1998

K981809

SURGICAL SOLUTIONS

510(k) Summary
(as required by section 807.92c)

Submitters name, address, phone and fax:

Chief Medical Officer
Surgical Solutions, L.L.C.
2550 Bluffwood Circle
Iowa City, IA 52245

Name of contact person:

Matthew A. Howard III, MD
Chief Medical Officer

Date of summary preparation:

May 21, 1998

Proprietary and (common) name:

Caroline Guide (Posterior Ventricular Catheter Guide)

Classification:

Stereotaxis Instrument, Regulatory class: II, Product code HAW 882.4560

Legally marketed device to which equivalence is being claimed:

Caroline Guide (K973277)

Description of the device:

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 a frontal target point.

The intended use:

The Caroline Guide is intended for use by neurosurgeons during posterior ventricular catheter placement procedures.

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

The modified Caroline Guide and original Caroline Guide (predicate device) have the following characteristics in common:

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

Description of non-clinical tests:

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. Pre-clinical testing demonstrated that the materials used in the construction of the Caroline Guide will withstand repeated decontamination, cleaning and sterilization cycles without adverse effects.

Discussion of clinical tests:

The Caroline Guide was tested in a clinical trial at the Universities of Iowa and Washington, involving both pediatric and adult patients. The trial results were reported in the peer reviewed scientific literature (Appendix F) in 1995. Non-commercial Caroline Guide prototypes have been used routinely in adult and pediatric cases since that time at the aforementioned university hospitals, as well as, at Children's Hospital, Washington University (St. Louis). No complications have been noted as a result of use of the Caroline Guide in pediatric patients.

In 1997, an "adult patient only" Caroline Guide received FDA 510(k) approval. This device is sold in conjunction with an adult burr hole localizer (the Delia Localizer). The Delia Localizer is not suitable for use in children. The modified Caroline Guide described in this submission is suitable for use in either adult (with the Delia Localizer) or pediatric (without the Delia Localizer) patients.

Conclusions drawn from the non-clinical and clinical tests:

These pre-clinical and clinical test data indicate that the new technologic features of the modified Caroline Guide do not adversely affect safety or effectiveness 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

AUG 14 1998

Matthew A. Howard, III, MD
Chief Medical Officer
Surgical Solution, L.L.C.
2550 Bluffwood Circle
Iowa City, Iowa 52245

Re: K981809
Trade Name: Caroline Guide
Regulatory Class: II
Product Code: HAW
Dated: May 21, 1998
Received: May 21, 1998

Dear Dr. Howard:

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

510(k) Number (if known): K981809

Device Name: Caroline Guide

Indications For Use:

Statement of indications for use:

The Caroline Guide is indicated for use by neurosurgeons for posterior ventricular catheter placement forpatients who are:

1) Adults or children
2) Have enlarged ventricles
3) Have no intracranial mass legions or any structural abnormalities other than hydrocephalus
4) 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)

Mark N Milhous

for CMW (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981809

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

SK-68