4/23/99

K991029

Summary of Safety and Effectiveness

Device Modification Name: RapidFlap Cranial Clamp

Name of previously cleared 510(k): Sevrain Cranial Clamp SCC100 - 510(k) K971252

Classification Name: Plate, Cranioplasty, Preformed, Non-Alterable

Product Code and Reference: 84 GXN (21 CFR - 882.5330)

Intended use: RapidFlap is indicated for the re-attachment of the bone flap after a craniotomy.

Device Modification Description: The modification to the SCC-100 device are as follows:

1. Attachment of upper and lower plates
   - SCC-100 identified a threaded stem attachment between the upper and lower plates
   - Modified RapidFlap device has a grooved post connection between the upper and lower plates.
2. The material
   - SCC-100 identifies commercially pure titanium, grade 2 material
   - Modified RapidFlap device is manufactured from titanium 6 Al 4 V alloy.
3. Sterility
   - SCC-100 device is nonsterile
   - Modified RapidFlap device will be marketed sterile (details described under sterility information).
4. Drawings for necessary instrumentation changes for application of modified device is included in Attachment I.

Potential Risks:

The potential risks associated with the RapidFlap are the same as with the Sevrain Cranial Clamp, SCC-100. The following are contraindicated in the package insert:

1. Patients with a decompression flap.
2. Active infection.
3. Patient conditions including, blood supply limitation, insufficient quantity or quality of bone, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
5. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
6. RapidFlap device has not been designed for use in pediatric neurosurgery. The effect of skull growth on retention is unknown.
7. Not intended for use in patients likely to require reoperation. This device has not been demonstrated clinically to be removable after long term implantation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 1999

Ms. Diana Preston
Regulatory Affairs Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K991029
Trade Name: RapidFlap Cranial Clamp
Regulatory Class: II
Product Code: GXN
Dated: March 26, 1999
Received: March 29, 1999

Dear Ms. Preston:

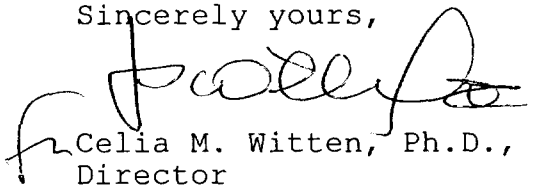
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4659. 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,



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): unknown

Device Name: RapidFlap Cranial Clamp

Indications For Use: RapidFlap is indicated for the re-attachment of the bone flap after a craniotomy.

(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 K991029

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)