K03-1034

MAY 21 2003

Page 1 of 1

Summary of Safety and Effectiveness

Device Modification Name: Spin down rapidflap

Name of previously cleared 510(k): Sevrain Cranial Clamp SCC100 - 510(k) K971252
RapidFlap Cranial Clamp - 51k(k) K9910229

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

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

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

Device Modification Description:

	Spin Down RapidFlap modification	K971252 Sevrain Cranial Clamp	K991029 RapidFlap Cranial Clamp
Attachment of upper and lower plates	Threaded stem attachment between the upper and lower plates	Threaded stem attachment between upper and lower plates	Grooved post connection between the upper and lower plates.
Material	CP Titanium and Titanium 6Al 4V alloy	CP Titanium, grade 2	Titanium 6Al 4V alloy
Sterility	Sterile	Non-Sterile	Sterile

Potential Risks:
The potential risks associated with the Spin Down RapidFlap are the same as with the Sevrain Cranial Clamp (K971252), SCC-100 and RapidFlap Cranial Clamp (K991029). The following are contraindicated in the package insert:

1. Patients with a decompression flap.
2. Active infection or latent infection.
3. Patient with insufficient quantity or quality of bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Ms. Kim Reed
Senior Regulatory Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218-2480

Re: K031034
Trade/Device Name: Spin Down RapidFlap
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: II
Product Code: GXN
Dated: March 31, 2003
Received: April 1, 2003

Dear Ms. Reed:

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 (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

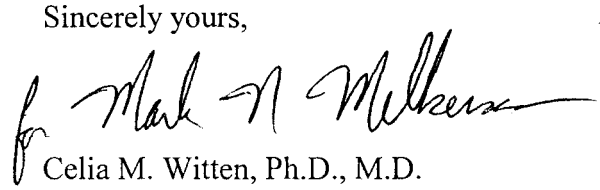
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and 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 (Sections 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. 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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

Enclosure

510(k) Number (if known): K03-1034

Device Name: Spin down rapidflap

Indications For Use:

Spin Down 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)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031034

Prescription Use___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)