

FEB 22 2000

K993990

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS:
LEIBINGER QUIK DISK TITANIUM CLAMP SYSTEM

General Information

| | |
|--------------------------------|---|
| Proprietary Name: | Leibinger Quik Disk Titanium Clamp System |
| Common Name: | Plate, Cranioplasty, Preformed, Non-Alterable |
| Classification Name(s): | Plate, Cranioplasty, Preformed, Non-Alterable |
| Classification Code(s): | GXN, 882.5330 |
| Submitter: | Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370 |
| Submitter's Registration #: | 1811755 |
| Manufacturer's Registration #: | 1811755 |
| Contact Person: | Kristyn R. Kelley Project Engineer Quality Assurance and Regulatory Affairs 800-253-7370 x5045 |
| Summary Preparation Date: | November 23, 1999 |

Device Description

The Leibinger Quik Disk Titanium Clamp System consists of a two-piece titanium implant and associated nonpowered neurosurgical instruments. The system allows for timely fixation of cranial flaps to the surrounding cranium after craniotomies in lieu of bone plate and screw methods. The Quik Disk has two parallel 15 mm diameter titanium disks that are connected by an internal, serrated breakaway stem and grasping clamp assembly that is fully contained between the two discs.

Intended Use

The Leibinger Quik Disk Titanium Clamp System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure.

Substantial Equivalence

The Leibinger Quik Disk Titanium Clamp System is substantially equivalent to the Aesculap Craniofix Titanium Clamp System (K972332), the Synthes Cranial Flap Twist Clamp (K991860) and the Walter Lorenz RapidFlap Cranial Clamp (K991029).

**FEB 22 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kristyn R. Kelley
Project Engineer
Quality Assurance and Regulatory Affairs
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K993990
Trade Name: Leibinger Quik Disk Titanium Clamp System
Regulatory Class: II
Product Code: GXN
Dated: November 23, 1999
Received: November 24, 1999

Dear Ms. Kelley:

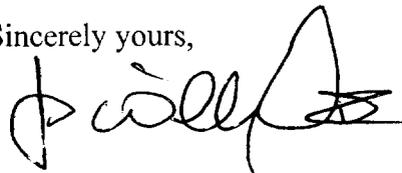
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 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 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Dillard III", written over a horizontal line.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~not known~~ K993990

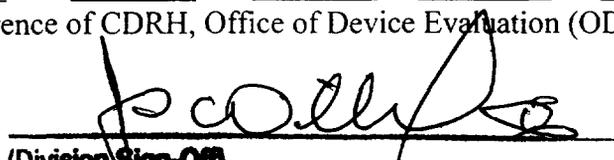
Device Name: Leibinger Quik Disk Titanium Clamp System

Indications For Use:

The Leibinger Quik Disk Titanium Clamp System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure.

(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 K993990

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)