Attachment 4

MAR 3 1 2004

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510(k) Summary

Herculon* Soft Tissue Reattachment System

United States Surgical
150 Glover Avenue
Norwalk, CT 06856
USA

DEVICE DESCRIPTION

The Herculon* Soft Tissue Reattachment System is a nonabsorbable repair device used to attach soft tissue to bone using sutures. The device is a self tapping, Ti-6Al-4V threaded implant that accommodates one or two sutures. The sterile package includes a Suture Anchor, Inserter, and polyester suture.

CLASSIFICATION NAME

Suture Anchor/Screw, Fixation, Bone

INDICATIONS FOR USE

The Herculon* Soft Tissue Reattachment System is indicated for the reapproximation of soft tissue.

MATERIALS:

All components of the Herculon* Soft Tissue Reattachment System are comprised of materials which are in accordance with ISO Standard #10993-1.

PREDICATE DEVICE

Ogden* Suture Anchor with Suture (K020352)

SUBSTANTIAL EQUIVALENCE*

The Herculon* Soft Tissue Reattachment System was claimed to be substantially equivalent* to the currently marketed version of the device. Information pertaining to this device was provided in the submission.

*Any claim of substantial equivalence is made exclusively in regard to the U.S. Food, Drug and Cosmetic Act and should not be viewed in any other light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

Mr. Chester McCoy
Director of Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K040594
Trade/Device Name: Herculon* Soft Tissue Reattachment System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 19, 2004
Received: March 8, 2003

Dear Mr. McCoy:

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 may be obtained 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,

for 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

Attachment 2

Indications for Use Statement

510(k) Number K040594

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040594

Device Name

Herculon* Soft Tissue Reattachment System

Indications For Use

The Herculon* Soft Tissue Reattachment System is intended for the reapproximation of soft tissue.

INDICATION	Procedures
SHOULDER	Bankart, Slap lesion, Rotator cuff, and Deltoid repair. Acromio-clavicular separation, capsular shift/capsulolabral reconstruction and Biceps tenodesis.
ELBOW	Tennis elbow repair, biceps tendon reattachment.
KNEE	Extra capsular repairs; reattachment of medial and lateral collateral ligaments, posterior oblique ligament or joint capsule to tibia, and joint capsule closure to anterior proximal tibia; Extra capsular reconstruction, ITB tenodesis, Patellar ligament and tendon avulsions.
ANKLE	Lateral and medial instability, Achilles tendon repair/reconstruction.
PELVIS	Fixation in pubic bone for the purpose of bladder neck suspension.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: No
(Per 21 CFR 801.109)