

K96 5228

510(k) SUMMARY OF INFORMATION:

NOV 10 1997

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856
(203) 845-1000

CONTACT PERSON: Craig M. Audet

DATE PREPARED: October 31, 1997

CLASSIFICATION NAME: Fastener, Fixation, Biodegradable Soft Tissue

COMMON NAME: Absorbable Implantable Staple

PROPRIETARY NAME: Trademark name not yet determined.

PREDICATE DEVICE: PDS II Suture, Ethicon, Inc.

DEVICE DESCRIPTION: The Surgical Dynamics™ Meniscal Staple** consists of a resorbable braid connecting the two resorbable legs of the staple. The staple is used in the approximation of soft tissue, specifically the meniscus. The device is made of a resorbable copolymer, a polyester derivative of lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis into lactic and glycolic acids which are then metabolized by the body.

INTENDED USE: The Surgical Dynamics™ Meniscal Staple** is indicated for the repair of vertical longitudinal full thickness tears (i.e., bucket-handle) in the red-red and red-white zones.

MATERIALS: All component materials of the Surgical Dynamics™ Meniscal Staple** and stapler are comprised of biosafe materials which are in accordance with ISO Standard #10993-1.

PERFORMANCE TESTING: In vitro and in vivo performance testing demonstrated Surgical Dynamics™ Meniscal Staple is suitable for use in the approximation of meniscal tissue.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Craig M. Audet
Director, Corporate Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

NOV 10 1997

Re: K965228
Surgical Dynamics™ Meniscal Staple
Regulatory Class: II
Product Code: MAI
Dated: August 11, 1997
Received: August 14, 1997

Dear Mr. Audet:

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.

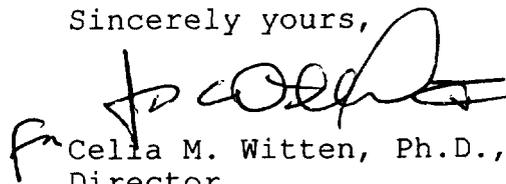
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Craig M. Audet

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

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

Surgical Dynamics™ Meniscal Staple**

II. Indications Page:

510(k) Number: K965228

Device Name: Surgical Dynamics™ Meniscal Staple**

Indications for Use: The Surgical Dynamics™ Meniscal Staple** is indicated for the repair of vertical longitudinal full thickness tears (i.e., bucket-handle) in the red-red and red-white zones.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____



(Division Sign-Off)
General Restorative Division
510(k) Number: K965228