

NOV. 3, 1997

IX. Summary of Safety and Effectiveness

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Sharon L. Murphy

DATE PREPARED: August 28, 1997

CLASSIFICATION NAME: Staple, Fixation, Bone

COMMON NAME: Pop Rivet

PROPRIETARY NAME: Surgical Dynamics* S•D sorb* E-Z Tac*

PREDICATE DEVICES: Surgical Dynamics* S•D sorb* E-Z Tac* (K961585)
Surgical Dynamics* S•D sorb* Suture Anchor (K961578)
Mitek GII Bone Anchor (K953877)

DEVICE DESCRIPTION: The Surgical Dynamics* S•D sorb* E-Z Tac* is an absorbable implant to be used for affixing soft tissue to bone.

INTENDED USE: The Surgical Dynamics* S•D sorb* E-Z Tac* is indicated for use in soft tissue to bone fixation for rotator cuff repairs and for reattachment of the glenoid labrum and/or inferior glenohumeral ligament.

MATERIALS: Like all the devices manufactured by United States Surgical Corporation, the Surgical Dynamics* S•D sorb* E-Z Tac* device is composed entirely of biocompatible materials which are in compliance with ISO 10993-1 for their intended patient contact profile.

cl



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1997

Ms. Sharon L. Murphy
Senior Regulatory Affairs Associate
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K973281
Trade Name: Surgical Dynamics*
SD sorb E-Z Tac*
Regulatory Class: II
Product Codes: MAI and JDR
Dated: August 28, 1997
Received: September 2, 1997

Dear Ms. Murphy:

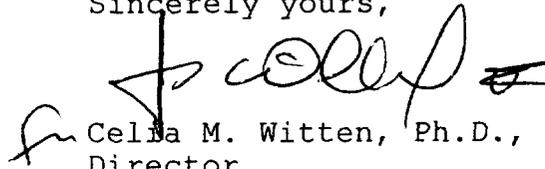
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

IV. Indications for Use

510(k) Number (if known): **K97.3281**

Device Name: Surgical Dynamics* EZ-Tac*

Indications For Use:

The Surgical Dynamics* S•D sorb* E-Z Tac* is indicated for use in soft tissue to bone fixation for **rotator cuff repairs and reattachment of the glenoid labrum and/or inferior glenohumeral ligament.**

please form behind this.

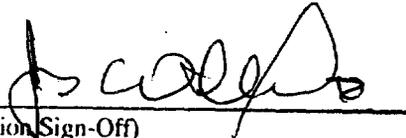
(Please do not write below this line - continue on another page if needed)

Concurrence of CDREI, Office of Device Evaluation (ODE)

Prescription Use: OR Over-The-Counter

Use: _____

(Per 21 CFR 801.109)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number **K973281**