3/1/99

K983318

Appendix 3
510(k) Summary

SUMMARY:	510(k) Summary of Information Supporting Safety and Effectiveness
SUBMITTER:	General Surgical Innovations, Inc. 10460 Bubb Road Cupertino, CA 95014 (408) 863 – 2500
CONTACT PERSON:	Ferolyn Powell
DATE PREPARED:	September 15, 1998
CLASSIFICATION NAME:	Endoscope and/or Accessories
COMMON NAME:	Fixation System
PROPRIETARY NAME:	Not yet determined
DEVICE DESCRIPTION:	The GSI Fixation System and the predicate devices are endoscopic multi-fire, fastening systems. The New Device and the Predicate Devices are single patient use, disposable and supplied sterile, with the exception of the Origin Tacker System which is supplied in two parts: the fastener cartridge is single use, disposable and the handle is reusable.
PREDICATE DEVICES:	Origin Tacker™ System AUTO SUTURE™ Modified Endoscopic Fascia Stapler Endoscopic Multifeed Stapler
INTENDED USE:	The New Device is intended for the same use as the Predicate Devices. All of these devices are intended for use either in minimally invasive, endoscopic or open surgical procedures. The indications statement for the New Device and the Predicate Devices is the same. All of the devices are used for approximating tissue and affixing prosthetic material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 1999

Mr. Ferolyn Powell
Vice President, Regulatory Affairs and
Quality Assurance
General Surgical Innovations
10460 Bubb Road
Cupertino, California 95014

Re: K983318
Trade Name: Fixation System
Regulatory Class: II
Product Code: GDW
Dated: December 16, 1998
Received: December 17, 1998

Dear Mr. Powell:

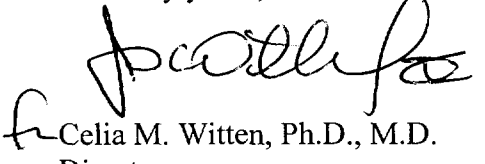
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 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) 594-4595. 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,



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

8.1 Statement of Indications for Use

510(k) Number (If known): K983318

Device Name:

Fixation System

Indications for Use:

The indications statement for the New Device and the Predicate Devices is the same. All of the devices are used for approximating tissue and affixing prosthetic material. Both endoscopic and open procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983318