OCT 2 2 2003

K032093 page 1/2

510(k) Summary
For the Sofradim Production
PARIEFIX ™ Endoscopic Stapler

1. SPONSOR/MANUFACTURER

Sofradim Production
116 avenue du Formans
01600 Trevoux
France

Contact: Christophe Cosson
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name:	PARIEFIX™
Common/Usual Name:	Endoscopic stapler/Laparoscopic accessory
Classification Name:	Endoscope and/or accessories

3. PREDICATE DEVICES

Ethicon Endopath® EMS	K913469
Origin Tacker® System	K944415
Phusis® Absorbable Interference Screw	K970879 [same PLA material]

4. DEVICE DESCRIPTION

The PARIEFIX device is an Endoscopic Stapler composed of a disposable delivery instrument and resorbable fixation devices. The PARIEFIX Delivery Instrument consists of an ergonomic handle, trigger, locking/unlocking mechanism, rotation knob, shaft containing ten fixation devices, and retractable hollow needle. The trigger, locking/unlocking mechanism, rotation knob, and hollow needle all function in the delivery of the fixation device to the tissue. A visual marker at the distal tip of the shaft indicates the position of the retractable needle to aid in placement of the fixation device. The resorbable fixation device consists of a connection pin, which connects the distal anchoring tip to the proximal tip. The distal anchoring tip

penetrates the biological tissues and, after back and forth motion, is anchored into the tissues. The proximal tip anchors the mesh to the biological tissues.

5. INTENDED USE

The PARIEFIX Endoscopic Stapler is indicated for approximation of soft tissues and fixation of surgical mesh to tissues during laparoscopic surgical procedures such as hernia repair.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The PARIEFIX Resorbable Fixation Device material is identical to that described in K970879 for the cleared Phusis® Absorbable Interference Screw.

The PARIEFIX device is substantially equivalent to the Ethicon Endopath® EMS and the Origin Tacker® system. The PARIEFIX device, the Ethicon Endopath® EMS, and the Origin Tacker® system have the same intended use in that they are all used for surgical mesh fixation via laparoscopic approach. All of the devices consist of a disposable endoscopic stapler delivering ten or more implantable fixation devices.

7. PERFORMANCE TESTING

Testing was performed to determine the performance characteristics of the PARIEFIX Resorbable Fixation Devices in comparison with the predicate devices. The test results showed that the Sofradim and predicate devices were similar in performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

Sofradim Production
c/o Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032093
Trade/Device Name: Sofradim PARIEFIX Endoscopic Stapler
Regulation Number: 21 CFR 876.1500, 21 CFR 878.4750
Regulation Name: Endoscope and/or accessories, Implantable staples
Regulatory Class: II
Product Code: GCJ, GDW
Dated: July 3, 2003
Received: July 28, 2003

Dear Ms. McNamara-Cullinane:

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 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,

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

K032093

510(k) Number (if known):

Device Name: Sofradim PARIEFIX Endoscopic Stapler

Indications for Use:

The PARIEFIX Endoscopic Stapler is indicated for approximation of soft tissues and fixation of surgical mesh to tissues during laparoscopic surgical procedures such as hernia repair.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032093

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)