510(k) Summary

SEP 26 2007

SAPI MED S.P.A.
Via Santi 25-Z.I. D4 Scalo
Alessandria, ITALY 15100
Phone 39-013-1348109

Contact: Mrs. Paola Oddenino

Summary Prepared: February 28, 2007

Trade Name: *LEM Hemorrhoidal Ligators*

Common Name: Hemorrhoidal Ligators

Classification Name: ligator, Hemorrhoidal

Predicate Device Identification:

CFR21:876.4400
Product Code:FHN
Device Class:II
Legally Marketed Device:

Company	*Product*	*510(k) #*
Patrick J. O'Regan	O'Regan Ligator	K963166
Erchinger Medizintechnik	Erchinger Hemrrohoidal ligator	K000297

Description:
The Sapimed LEM Disposable hemorrhoidal ligators are used to apply a ligature or elastic ring around the base of the hemorrhoidal nodule in order to cut off the blood flow to hemorrhoidal tissue. The lack of blood supply will result in shrinkage, desiccation and elimination of the hemorrhoid. It is supplied in two models Model numbers A.5650 and A 5660. They are both manufactured from plastic and designed for single patient use. Both variants are supplied with a separable cylindrical cone (Ø 10mm) to assist in loading the bands, an angled distal cylinder to contain the nodule, and an ergonomically-designed pistol handgrip,with trigger to release the banding ring. The LEM has an angled design that allows the operator a clear view of the procedure.

Intended Use:

The LEM Hemorrhoidal ligators are used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

Hemorrhoidal ligators are intended for exclusive use by medical personnel trained in proctology procedures.

Device Comparison Table: Predicate Product Comparison Chart

Parameter			
Device Name	**LEM Hemorrhoidal Ligator**	**O'Regan Ligator**	**Erchinger Hemorrhoidal Ligator**
Product Code	FHN	FHN	FHN
K Number		K963166	K000297
Common Name	Hemorrhoidal ligator	Hemorrhoidal ligator	Hemorrhoidal legator: suction ligators
Intended Use	LEM hemorrhoidal ligators are used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.	O'Regans ligiator are used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.	Hemorrhoidal ligators are used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.
Material	Plastic	Plastic	Surgical Stainless steel
Single use	Yes	Yes	No
Method of use	Lem hemorroidal ligators are used to apply a ligature or elastic ring around the base of the hemorrhoidal nodule in order to cut off the blood flow to hemorrhoidal tissue. Two models for use either with forceps or suction. Both variants are supplied with a separable cylindrical cone) to assist in loading the bands, an angled distal cylinder to contain the nodule, and an ergonomically-designed pistol handgrip,with trigger to release the banding ring. re	O'Regan ligator provides suction and ligation capability. An elastic band can be stretched over the front end of the ligator by means of the cone shaped loading apparatus. The front end of the ligator is inserted through the anus deep within the rectum. The nozzle is then withdrawn gently as the device is angulated to point directly towards the site to be banded which is then trapped and banded.	The hemorrhoid is grasped with a forceps or sucked into the ligator head (suction forceps) A rubber ring is slipped over the varicosity, causing tissue necrosis and sloughing of the hemorrhoid
Packaged	Clean, non-sterile	Clean, non sterile	Clean, non-sterile

Similarities and differences between LEM Hemorrhoidal Ligators and Predicate Products

The LEM hemorrhoidal ligators have the same intended use as the predicate devices using a retrieval of the nodule through suction or forceps and the consequent banding of the nodule. The difference between the LEM hemorrhoidal ligator and the O'Regan ligator is the ergonomically designed handgrip rather than the syringe-like handle of the the O'Regan ligator. The Erchinger ligator is a reuseable stainless steel rather than a single use device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 26 2007

Sapimed S.P.A.
c/o Ms. Yolanda Smith
Smith Associates
1676 Village Green, Suite A
CROFTON MD 21114

Re: K070881
Trade/Device Name: LEM Suction Hemorrhoidal Ligator
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: FHN
Dated: August 21, 2007
Received: August 22, 2007

Dear Ms. Smith:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070881

Device Name: LEM Suction Hemorrhoidal Ligator

Indications for Use:

The LEM Hemorrhoidal ligators are used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

Hemorrhoidal ligators are intended for exclusive use by medical personnel trained in proctology procedures.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070881