K091519

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21-May-09

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JUL 28 2009

Official Contact: Colin Foster – Managing Director

Proprietary or Trade Name: Multi-Ligator

Common/Usual Name: Hemorrhoidal ligators

Classification Name/Code: 78 FHN – hemorrhoidal ligators
21 CFR 876.4400

Device: Multi-Ligator

Predicate Devices: K0000297 – Erchinger Medizintecknik – Ligator
K070881 – SAPI MED S.p.a. – LEM ligator

Device Description:
The Haemoband Multi-Ligator is a simple handheld device which allows the user to hold the hemorrhoid tissue with an applied suction while slipping a ligation band around the tissue.

The Haemoband Multi-Ligator is a disposable device for the rubber band ligation of hemorrhoids. It is for single use only and is supplied with 4 preloaded non-latex rubber bands.

Indications for Use:
The Haemoband Multi-Ligator includes suction and ligation capabilities. The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

Patient Population:
Individuals with hemorrhoids

Environment of Use:
Hospitals, clinics, and doctors' offices.

Contraindications

Do not use to treat:

- 4th degree or continuously prolapsed hemorrhoids
- Anal Polyps
- In the presence of perineal infection, can be used after the infection has settled.
- Use with caution when treating patients on anticoagulants i.e. Warfarin

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Summary of substantial equivalence:

	Proposed Device	Predicate Device	
510(k) Numbers & Manufacturers		**K070881 SAPI MED S.p.a.**	**K000297 Erchinger Medizintechnik**
Device	**Haemoband Multi-Ligator**	**LEM**	**Ligator**
Class	Class II	Class II	Class II
Product Code	FHN	FHN	FHN
CFR	876.4400	876.4400	876.4400
Intended Use	The Haemoband Multi-Ligator includes suction and ligation capabilities. The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.	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 used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.
Environment of Use	Hospitals, clinics, and doctors' offices.	Not specified	Not specified
Prescriptive	Yes trained medical personnel	Yes trained medical personnel trained in proctology	Yes trained medical personnel trained in proctology
Principle of Operation	Apply a ligature or elastic ring around the base of the hemorrhoidal nodule in order to cut off the blood flow to the hemorrhoidal tissue. Has a means to apply suction to hold the hemorrhoidal tissue prior to and during the ligature procedure. Pre-loaded bands in a pistol handgrip with trigger to apply suction and release the banding ring	Apply a ligature or elastic ring around the base of the hemorrhoidal nodule in order to cut off the blood flow to the hemorrhoidal tissue. Has a means to apply suction to hold the hemorrhoidal tissue prior to and during the ligature procedure. Pre-loaded bands in a pistol handgrip with trigger to apply suction and release the banding ring	Hemorrhoid is grasped with a forceps or sucked into the ligator head (suction forceps). A ring is slipped over the varicosity, causing tissue necrosis and sloughing of the hemorrhoid.
Disposable	Single patient use, disposable	Single patient use, disposable	Surgical stainless steel, reusable
Materials	Standard materials tested or certified to ISO 10993 Bands identical to K000297	Not known	Identical bands used in proposed device.

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510(k) Numbers & Manufacturers		K070881 SAPI MED S.p.a.	K000297 Erchinger Medizintechnik
Device	**Haemoband Multi-Ligator**	**LEM**	**Ligator**
Preloaded ready for use	Yes	No but supplied with a band loader	No
Multi bands	Yes	No	No
Auto reload	Yes	No	No
Suction	Integrated	Yes	Yes

It is our view that there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

Substantial Equivalence

The Haemoband Multi-Ligator is viewed as substantially equivalent to the predicate devices because:

Indications –
- Identical to predicate – K070881 – SAPI Med - LEM

Technology –
- Similar technology used –
  - K000297 – Erchinger
  - K070881 – SAPI Med

Materials –
- The materials in patient contact are identical to predicate device or we have provided ISO 10993 certification.

Environment of Use –
- Identical to predicate – K000297 – Erchinger

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Haemoband Surgical Ltd.
c/o Mr. Paul E. Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134-29158

JUL 2 8 2009

Re: K091519
Trade/Device Name: Haemoband Multi-Ligator
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class; II
Product Code: FHN
Dated: May 21, 2009
Received: May 22, 2009

Dear Mr. Dryden:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K091519 (To be assigned)

Device Name: Haemoband Multi-Ligator

Indications for Use:

The Haemoband Multi-Ligator includes suction and ligation capabilities. The ligator is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

It is for use only by trained medical personnel.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091519