510(k) Summary for the THD Bandy

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.1. General Information

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Summary Preparation Date: October 27, 2009

2.2. Names

Device Name: THD Bandy
Classification Name: Hemorrhoidal ligator
Product Code: FHN
Regulation number: 876.4400

2.3. Predicate Devices

The THD Bandy is substantially equivalent to the following devices:

Applicant	*Device name*	*510(k) Number*
Sapimed S.p.A.	LEM	K070881
Haemoband Surgical LTD	Haemoband Multi Ligator	K091519
THD S.p.A.	THD Disposable Anoscope/Proctoscope	K080132

The THD Bandy is substantial equivalent to the predicate devices. The design characteristics are similar to the Sapimed model number A.5650 (LEM model for use with suction - K070881). The intended use of THD Bandy is the same as Sapimed LEM (K070881).
Both THD Bandy and Sapimed LEM (K070881) are manufacture in plastic material, are designed with similar dimensions and are single use devices. The THD Bandy is equivalent to the Sapimed LEM (K070881) and to the Haemoband Multi Ligator Device (K091519) and to the THD Disposable Anoscope/Proctoscope (K080132) concerning the labeling information.

2.4. Device Description

The THD Bandy is an hemorrhoidal ligator intended for pinching off hemorrhoidal nodule. The device is to be used in combination with a suction device, mounted on the basis of the THD Bandy. The THD Bandy consists of a ligation unit, a pusher and a cone. The ligation unit consists of a cylindrical housing connected with a trigger for the release of the elastic band or of the ligature. The hemorrhoidal nodule, trapped on the distal portion of the device, receive an elastic ring or a ligature in order to cut off the blood flow. The pusher and the cylindrical cone are provided in order to assist in the loading of the bands.

2.5. Indications for Use

The THD Bandy is used to cut off the blood flow to hemorrhoidal tissue by means of a elastic band or a ligature placed around the hemorrhoid base.
The THD Bandy is to be used for exclusive use by medical personnel trained in proctology procedures.

2.6. Performance Data

Performance characteristics of device are equivalent to the Predicate Devices.
The THD Bandy has been developed and tested according to the following international standards:

- ✓ ISO 10993-1:2003, Biological evaluation of medical devices - Part 1: Evaluation and testing. (Biocompatibility) - *FDA Recognition Number 2-98*
- ✓ CEN EN 980:1996+A1:1999+A2:2001, Graphical Symbols for Use in the Labelling of Medical Devices. - *FDA Recognition Number 5-32*
- ✓ ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General) – *FDA Recognition Number 5-40*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

THD S.p.A
c/o Mr. Guido Bonapace
President and Regulatory Consultant
ISEMED S.r.l.
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Imola, BO
ITALY 40026

JUL 15 2010

Re: K093497
Trade/Device Name: THD Bandy
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: FHN
Dated: July 5, 2010
Received: July 7, 2010

Dear Mr. Bonapace:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

JUL 15 2010

510(k) Number (if known): K093497

Device Name: THD Bandy

Indications for Use:

The THD Bandy is used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or ring placed around the hemorrhoid base.

The THD Bandy is to be used for exclusive use by medical personnel trained in proctology procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ ____ (21 CFR 801 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 K093497