K090432

MAY 29 2009

510(k) Summary

Official contact:

ANGIOLOGICA B.M. S.r.l.
Via Giovanni XXIII, 4 – 27028
San Martino Siccomario (PV) – Italy
contact person: Roberto Manca
telephone: +39 0382 556616
fax number: +39 0382 556191
e-mail: quality@angiologica.com
Date: 18/02/2009

Trade names:

HEMORPEX SYSTEM (HPS);

Common name:

DISPOSABLE ANOSCOPE

Classification name:

ANOSCOPE AND ACCESSORIES

Predicate devices:
The HEMORPEX SYSTEM (HPS) - produced by ANGIOLOGICA B.M. S.r.l. - is substantially equivalent to the SAPIMED DISPOSABLE ANOSCOPE.

Description:
HEMORPEX SYSTEM (HPS) is a diagnostic and operating anoscope, which is mainly intended for the surgical treatment of the hemorrhodal disease through dearterializing hemorrhoidopexy.

HemorPex System (HPS) is a device made by a fixed part which remains in contact with the anoderma and the sensible mucosa of the anal canal, and by a rotating operative part which includes the window through which the suture stitches are posed.
The instrument has 6 preset positions of the operative window. In these positions there are the 6 terminal branches of the superior hemorrhoidal artery.

Intended use:
The HEMORPEX SYSTEM (HPS) is intended for physician use to examine the anal sphincter and anus and to perform several diagnostic and therapeutic procedures, such as surgical treatment for hemorrhoidal disease.

Comparison to predicate devices:
The HEMORPEX SYSTEM (HPS) have the same intended use, the same target population, the same kind of contact and the same technological characteristics (materials, sterility, general shape).

DEVICE NAME	ANGIOLOGICA	PREDICATE DEVICE
	HEMORPEX SYSTEM (HPS)	SAPIMED
PRODUCT CODE	FER	FER
K NUMBER	K090432	K070913
COMMON NAME	Disposable Anoscope	Disposable Anoscope
INTENDED USE	The HEMORPEX SYSTEM (HPS) is intended for physician use to examine the anal sphincter and anus and to perform several diagnostic and therapeutic procedures, such as surgical treatment for hemorrhoidal disease.	Intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures
MATERIAL	Plastic	Plastic
SINGLE USE	YES	YES
PACKAGED	Sterile	Clean, non-sterile/sterile

Differences between ANGIOLOGICA B.M. S.r.l. HEMORPEX SYSTEM (HPS) and the predicate device should not affect the safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2009

Mr. Roberto Manca
Quality Manager
Angiologica B.M. s.r.l.
4 Via Giovanni XXIII
San Martino Siccomario (PV) 27028
ITALY

Re: K090432
Trade/Device Name: Hemorpex System (HPS)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FER
Dated: May 5, 2009
Received: May 6, 2009

Dear Mr. Manca:

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 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.

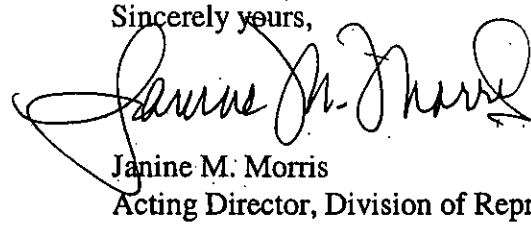
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.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). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

510(k) Number (if known): **K090432**

Device Name: HEMORPEX SYSTEM (HPS)

Indications For Use:

The HEMORPEX SYSTEM (HPS) is intended for physician use to examine the anal sphincter and anus and to perform several diagnostic and therapeutic procedures, such as surgical treatment for hemorrhoidal disease.

Prescription Use ___N/A___ AND/OR Over-The-Counter Use ___N/A___
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K090432