510(k) Summary

K070915

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SAPIMED S.P.A.
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Phone 39-013-1348109

JUL - 6 2007

Contact: Mrs. Paola Oddenino

Summary Prepared: February 28, 2007

Trade Name: *Disposable Sigmoidoscope/*

Common Name: Disposable Sigmoidoscope/Proctoscope

Classification Name: Endoscope And/Or Accessories

Predicate Device Identification:

CFR21:876.1500
Product Code:KOG
Device Class:II
Legally Marketed Device:

Company	*Product*	*510(k) #*
Welch Allyn, Inc	Disposable Sigmoidoscope Model#53125	K770291

Description:
The Proctoscopy set consists of a multi-use plastic Grip (Ref. A.4131) and a choice of 3 different single use Insertion Tubes (Ref. A.4113, A.4120, A.4125). Each insertion tube comes with a matching obturator to facilitate the atraumatic insertion of the tube into the rectum.

The multi-use plastic Grip (Ref. A.4131) consists of the following elements:

1. A hollow handle designed to connect to the light source (either a fiberoptic cable or a pen-light).
2. A circular frontal opening designed to connect to the Insertion Tube.
3. A posterior hinged closure containing both the lens and the insufflator attachment.

The insufflator is a hand squeeze ball with a one-way valve as also used in manual blood pressure measuring devices.

The Sigmoidoscope Kit MRP (ref. A.4522) consists of a Rigid Proctosigmoidoscope insertion tube and a plastic grip.

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Sapimed Sigmoidoscopes are intended for exclusive use by medical personnel trained in proctology procedures.

Intended Use:
SAPIMED's Sigmoidoscopes are used to examine the rectum and lower bowel and, using additional accessories, perform various diagnostic and/or therapeutic procedures.

Predicate Product Comparison Chart:

Parameter		
Device Name	**Disposable Sigmoidoscope/Sigmoidoscope**	**Welch Allyn Disposable sigmoidoscope**
Product Code	KOG	KOG
K Number		K770291
Common Name	Disposable Sigmoidoscope	Disposable sigmoidoscope
Intended Use	SAPIMED's Sigmoidoscopes are used to examine the rectum and lower bowel and, using additional accessories, perform various diagnostic and/or therapeutic procedures.	SAPIMED's Sigmoidoscopes are used to examine the rectum and lower bowel and, using additional accessories, perform various diagnostic and/or therapeutic procedures.
Material	Plastic	plastic
Single use	Yes	Yes
A.4113, A.4120, A.4125	Clean, non-sterile	Clean, non-sterile
A.4522 Sigmoidoscope Kit MRP	Sterile	

Similarities and differences between Sapimed Disposable Sigmoidoscope and Predicate Products
The Sapimed disposable sigmoidoscopes have a similar intended use, technological characteristics and mode of operation as the predicate products, both disposable and reuseable and presents no new questions concerning safety and efficacy.

Shelf Life
Accelerated aging testing was performed to substantiate an expiration of 5 years.

Biocompatibility Testing:
ISO10993 standards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 6 2007

SAPI Med S.p.A.
c/o Ms. Yolanda Smith
Smith & Associates Consultants
1676 Village Green, Suite A
CROFTON MD 21114

Re: K070915
Trade/Device Name: Sapimed Disposable Sigmoidoscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KDM
Dated: June 1, 2007
Received: June 4, 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/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): K 070915

Device Name: Sapimed Disposable Sigmoidosocope

Indications for Use:

SAPIMED's Sigmoidoscopes are used to examine the rectum and lower bowel and, using additional accessories, perform various diagnostic and/or therapeutic 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 K070915