510(K) Summary

OCT 12 2007

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

The assigned 510(k) number is: K070845

Submitter / Distributor:

Sounmed, Inc.
6800 N.W. 77th Court
Miami, Fl 33166

Telephone: 305-477-0986
Fax: 305-477-5351

- **Contact Person:**

Jhoana Lores
Email: jhoana@sounmed.com

Manufacturer:

POLOS S.A
10, Amissou str.., GR 551 Kalamaria
Thessaloniki
Greece

- **Date Prepared**:

March 23, 2007

Name of the device:

- **Trade/Proprietary Name:** Sounmed Colposcopes
  COLPO-99
  COLPO 99 PLUS
- **Common Name:** Colposcope
- **Classification:**

Device Class: II Product Code: 85 HEX Regulation #: 884.1630

Legally Marketed Predicate Device:

DVF CPG Colposcope, K021854, DF Vasconcellos, SA

Device Description:

The ColposcopeS COLPO-99 / 99 PLUS is a precise optical instrument designed specially for the gynecologic examination. The Sounmed colposcope can be used to view vaginal en cervical tissues using stereoscopic optics.

The COLPO-99/ 99 PLUS Colposcope has detailed features that include a wide field of view, long focal length, uniform illumination, adjustable brightness, ease operation, and exceptional optics. It is an essential instrument for any gynecologic examination. The general features of the device are as follows:

- Eyepiece Magnification: 12.5X with diopter adjustment
- Focal Length: 300mm
- Green filter light.
- Easy replacement of halogen light bulb
- Ball joint gives you 360° easy motion for gross focus.

Statement of Intended Use:

The Sounmed Colposcope is a device designed to permit viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. A Colposcope is used to diagnose abnormalities and select areas for biopsy.

Comparison to predicate devices:

The Sounmed (subject device), and Vasconcello Colposcope are intended to permit direct viewing and imaging of the tissues of the vagina, cervix and external genital to diagnose abnormalities and select areas for biopsy. The Vansconcello colposcope rely on similar style of zoom optical systems and objectives that provide the necessary working distances required for patient observation. Both devices are offered with similar floor stand.

Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following standards were met:

- EN 60601-1-1
- EN 60601-1-2
- ISO 14971:2000

Discussion of Clinical Tests Performed:

Not Applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2007

Mr. Ruben Olivares
CEO
Sounmed, Inc.
Regulatory Affairs Department
6800 N.W. 77th Court
MIAMI FL 33166

Re: K070845
Trade Name: Colposcope COLPO-99/99 Plus
Regulation Number: 21 CFR §884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: October 8, 2007
Received: October 12, 2007

Dear Mr. Olivares:

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 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 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.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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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): K070845

Device Name: Sounmed Colposcope COLPO-99 / 99 PLUS

Indications For Use:

The Sounmed Colposcope COLPO-99 is intended to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070845