K110766 p 1 of 3

510(k) Summary
807.92(c)

SEP 15 2011

SPONSOR **807.92(a)(1)**

Company Name:	KOLPLAST CI LTDA
Company Address	312/318 Mundo Novo Sao Paulo, Brazil 05028-030
Telephone:	011 55 11 4496 1404
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Contact Person:	Daniela Feracin Pertpetuo

Summary Preparation Date: March 15, 2011

DEVICE NAME **807.92(a)(2)**

Trade Name:	KOLPLUX System
Common/Usual Name:	Vaginal Speculum Illumination System
Classification Name:	Speculum, Vaginal, Nonmetal
Regulation Number:	884.4530
Product Code:	HIB
Device Class:	II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Welch Allyn Inc.	Kleenspec Single Use Vaginal Speculum & 790 Series Cordless Illumination System	K070964

DEVICE DESCRIPTION **807.92(a)(4)**

The KOLPLUX System consists of a power source adapter, 2 meter long electrical cord, and the illumination system body and a carrying case. The Illumination System Body accommodates the LED and provides a keyhole female opening for the insertion of the optic fiber tube (found on the vaginal speculum).

Indication for Use **807.92(a)(5)**

The KOLPLUX System when used with a vaginal speculum provides illumination during pelvic examination and other gynecological procedures, such as pap smears, dilation and curettage (D&C), biopsy, and electrosurgery.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Predicate Product Comparison Table

Parameter	Kolplast KOLPLUX System	Welch Allyn KleenSpec® Vaginal Specula Illumination System
510(k) Number		K070964
Indications for Use	The KOLPLUX System when used with a vaginal speculum provides illumination during pelvic examination and other gynecological procedures, such as pap smears, dilation and curettage (D&C), biopsy, and electrosurgery.	KleenSpec® Vaginal Specula Illumination System when used with the vaginal, the cordless illuminator provides illumination during pelvic examinations and other gynecological procedures, such as pap smears, dilation and curettage (D&C), biopsy, and electrosurgery
Input	115-220 V – 60Hz, 11,5 VA	120V – 60Hz, 100mA
Output	3.5 VAC, 400 mA	4.7 VAC, 850 mA
Physical Specifications		
• Illuminator	Ø 33 mm x 48 mm	91.4 cm (36 in)
• Transformer	80 x 57 x 48 mm	183 cm (72 in)
Illumination		
• Lamp Life	2.600	100 Hours
• Lamp Voltage	4.71V	4.6 V
Operating Environment		
• Operating	+10° C to +35° C	+10° C to +35° C
• Transport/Storage	-20°C to +49° C	-20°C to +49° C
Intermittent Operation	60 minutes on max: 10 minutes off min	10 minutes on max: 5 minutes off min

NONCLINICAL TEST **807.92(b) (**

The KOLPLUX System is compliant to the Following international standards: UL60601-1 (2003), 1st Edition Medical Electrical Equipment, Part 1, General Requirements for Safety IEC 60601-2 (2001), 2ns Edition Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic compatibility

CONCLUSION **807.92(b)(3)**

The KOLPLUX System is similar to the Welch Allyn KleenSpec® Vaginal Specula Illumination System as it relates to indications for use and both provide illumination during pelvic examination.

Differences

The Welch Allyn KleenSpec® Vaginal Specula Illumination System is a cordless device whereas, the KOLPLUX System is not.

The KOLPLUX System introduces no new questions concerning safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Kolplast ci Ltda
% Mr. E.J. Smith
Consultant
Smith Associates
1468 Harwell Ave.
CROFTON MD 21114

SEP 15 20[illegible]

Re: K110766
Trade/Device Name: KOLPLUX System
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric – gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: August 3, 2011
Received: August 5, 2011

Dear Mr. 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. 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K110766

Device Name: KOLPLUX System

Indications for Use:

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Prescription Use ✓ (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, Gastro-Renal, and Urological Devices
510(k) Number K110766