

**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		
<i>Company</i>	<i>Product</i>	<i>510(k) #</i>
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 electro-surgery.

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 electro-surgery.	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 electro-surgery
Input	115-220 V – 60Hz, 11,5 VA	120V – 60Hz, 100mA
Output	3.5 VAC, 400 mA	4.7 VAC, 850 mA
<b>Physical Specifications</b>		
• Illuminator	Ø 33 mm x 48 mm	91.4 cm (36 in)
• Transformer	80 x 57 x 48 mm	183 cm (72 in)
<b>Illumination</b>		
• Lamp Life	2.600	100 Hours
• Lamp Voltage	4.71V	4.6 V
<b>Operating Environment</b>		
• 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), 1<sup>st</sup> Edition Medical Electrical Equipment, Part 1, General  
Requirements for Safety IEC 60601-2 (2001), 2<sup>nd</sup> 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

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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 2011

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: H1B  
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.

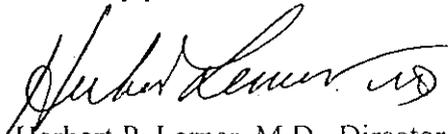
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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:

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.

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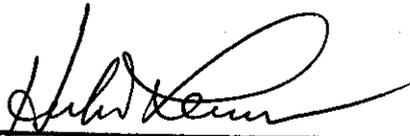
Prescription Use   
(Part 21 CFR 801 Subpart D)

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

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