14. Premarket Notification [510(k)] Summary

MAY 18 2007

Submitted By: Welch Allyn, Inc.
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Contact: John E. Sawyer, Vice-President, Quality Assurance & Regulatory Affairs

Common Name: speculum, vaginal, nonmetal

Trade Name: KleenSpec® Single Use Vaginal Speculum and 790 series Cordless Illumination System (Special 510(k))

Classification: 21 CFR § 884.4530; Class II

Predicate Device: KleenSpec Disposable Vaginal Speculum 580 series (K941272)

Description: The disposable vaginal speculum is used to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures such as: Pap smears, dilation and curettage (D&C), biopsy, & electrosurgery. Models with a smoke tube assembled to the upper blade can be connected to a separate smoke evacuator during electrosurgical procedures. The vaginal speculum can be used with or without the illuminator.

When used with the vaginal speculum, the cordless illuminator provides illumination during pelvic examinations. The illuminator can be used independent of the speculum as a general-purpose light source.

Intended Use: KleenSpec® Single Use Vaginal Speculum

The disposable vaginal speculum is used to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures.

The vaginal speculum can be used with or without the illuminator.

KleenSpec® 790 Series Cordless Illuminator

When used with the vaginal speculum, the cordless illuminator provides illumination during pelvic examinations and other

gynecological procedures, such as pap smears, dilation and curettage (D&C), biopsy, and electrosurgery.

The illuminator can be used independent of the speculum as a general-purpose light source.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 18 2007

Chris Horacek
VP and Associate General Counsel
Welch Allyn, Inc.
4341 State Street Road
SKANEATELES FALLS NY 13153-0220

Re: K070964
Trade/Device Name: KleenSpec® Single Use Vaginal Speculum and 790 series Cordless Illumination System
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: April 4, 2007
Received: April 5, 2007

Dear Mr. Horacek:

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

13. Statement of Indications For Use

510(k) Number (if known): K070964

Device Name: KleenSpec® Single Use Vaginal Speculum and 790 series Cordless Illumination System

Indications For Use: KleenSpec® Single Use Vaginal Speculum

The disposable vaginal speculum is used to dilate the vagina and expose the interior of the vagina and exterior of the cervix during pelvic examinations and other gynecological procedures.

The vaginal speculum can be used with or without the illuminator.

KleenSpec® 790 Series Cordless Illuminator

When used with the vaginal speculum, the cordless illuminator provides illumination during pelvic examinations and other gynecological procedures, such as pap smears, dilation and curettage (D&C), biopsy, and electrosurgery.

The illuminator can be used independent of the speculum as a general-purpose light source.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 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 K070964