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510(k) Summary

[As described in 21 CFR 807.92]

MAR 2 3 2012

Submitted by: Welch Allyn Inc.
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Skaneateles Falls, NY 13153-0220

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Date Prepared: February 23, 2012

Trade Name: KleenSpec® Single Use Vaginal Speculum

Device Classification Name: Speculum, Vaginal, Nonmetal

Device Classification: Class II

Classification Reference: 884.4530

Classification Product Code: HIB

Predicate Devices: KleenSpec® Single Use Vaginal Speculum and 790 series Cordless Illumination System
510(k) Number K070964

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.

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

This product is available for sale only upon the order of a physician or licensed health care professional.

Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate KleenSpec® Single Use Vaginal Speculum. The addition of the extra small size vaginal speculum does not introduce any new concerns regarding safety or efficacy. The designs have been demonstrated as substantial equivalent using bench test data.

Both the new size and the previously cleared KleenSpec® Single Use Vaginal Speculums are made of the same materials, which have biocompatibility testing according to FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993 requirements for limited contact duration, surface contacting, mucosal membrane device and are demonstrated to be suitable for the intended use of this product.

Non-Clinical Tests:
Verification and validation tests were conducted in accordance with Welch Allyn design control procedure. They are tested using established testing procedures to ensure the products performance parameters conform to the product design specifications.

The following standards were applied to the modified device.

Standard Identification Number	*Title*
ISO 14971	Medical Devices – Application of Risk management to Medical Devices

Clinical Performance Data:
No clinical studies were necessary or utilized for the purpose of obtaining safety or effectiveness data.

Conclusion:
Based on the information presented in this 510(k) premarket notification, Welch Allyn's KleenSpec® Single Use Vaginal Speculum modified to introduce a smaller size is considered substantially equivalent (as safe, as effective and performs as well as) to the currently marketed KleenSpec® Single Use Vaginal Specula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kevin Crossen
Director, Regulatory Affairs
Welch Allyn, Inc.
4341 State Street Road
SKANEATELES FALLS NY 13153

MAR 23 2012

Re: K120743
Trade/Device Name: KleenSpec® Single Use Vaginal Speculum
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: March 8, 2012
Received: March 12, 2012

Dear Mr. Crossen:

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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications For Use

510(k) Number (if known): K120743

Device Name: KleenSpec® Single Use Vaginal Speculum

Indications For Use: KleenSpec® Single Use Vaginal Speculum

KleenSpec® Single Use Vaginal Speculum

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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, Gastro-Renal, and Urological Devices
510(k) Number K120743