# 510(k) Summary

**Date:** July 23, 2013

**Submitted by:** ClearSpec LLC
131 NW 13th Street, Suite 38
Boca Raton, FL 33432

Phone: 561-395-7767
Fax: 561-237-5040

Contact: Navroze Mehta

**Common Name:** Vaginal Speculum

AUG 0 6 2013

**Trade Name:** **ClearSpec® Single-Use Vaginal Speculum**

**Classification Name:** Speculum, Vaginal, Nonmetal

**Classification:** Class II per 21 CFR 884.4530, Product Code: HIB

**Predicate Device:** Gongdong Disposable Vaginal Speculum (K050887)
Welch Allyn KleenSpec® Single Use Vaginal Speculum (K120743)

**Device Description:**

The ClearSpec® Single Use Vaginal Speculum is a disposable vaginal speculum constructed of polystyrene, used to dilate the vagina and expose the interior of the vagina and exterior of the cervix, and employs a unique flexible polyurethane sheath that is designed to assist in keeping the lateral walls of the vagina clear of the viewing area. The vaginal speculum can be used with or without an illuminator.
The ClearSpec® Single Use Vaginal Speculum is made available in various sizes from extra small to large to accommodate vagina cavity size.

**Indications for Use:**

The **ClearSpec® Single-Use 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.

**Technological Characteristics:**

The subject device has the same technological characteristics and indications for use as the predicate Gongdong Disposable Vaginal Speculum and Welch Allyn KleenSpec® Single Use Vaginal Speculum. The addition of a sheath surrounding the device blades to aid in retaining lateral vaginal tissue does not introduce any new concerns regarding safety or effectiveness. The designs have been demonstrated as substantial equivalent using bench testing.

The **ClearSpec® Single-Use Vaginal Speculum** and identified predicate devices are constructed of similar material commonly used throughout the medical device industry for like and similar devices and have been tested for biocompatibility per FDA GPM G95-1 and ISO 10993-1 requirements for limited contact duration, surface contacting mucousal membrane device and found to be suitable for the intended use of this product.

**Intended Use:**

The **ClearSpec® Single-Use 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.

**Testing:**

Bench testing has been conducted using simulated actual use conditions comparing the new device with the addition of the sheath to that of original speculum without the sheath. The results of the testing show the new device to perform as intended and equivalent to the predicate device. Testing included sheath material ability to survive stresses encountered during use without failure and sufficiency of sheath to speculum bond strength such that the sheath does not detach from the speculum during insertion, during the examination, or during withdrawal.

**Conclusion:**

In accordance with the Food, Drug, and Cosmetic Act and 21 CFR 807, and based on the information provided in the premarket notification application, **ClearSpec LLC** concludes that the **ClearSpec® Single-Use Vaginal Speculum** is substantially equivalent to the predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 6, 2013

ClearSpec, LLC
% Ira Duesler
Consultant
603 Grant Street
Herkimer, NY 13350

Re: K130046
Trade/Device Name: ClearSpec® Single-Use Vaginal Speculum
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: July 8, 2013
Received: July 9, 2013

Dear Ira Duesler,

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,

Glenn B. Bell -S

for 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

Indications For Use

510(k) Number: K130046

Device Name: ClearSpec® Single-Use Vaginal Speculum

Indications For Use:

The **ClearSpec® Single-Use 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.

Prescription Device X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Glenn B. Bell -S

**(Division Sign-Off)**
**Division of Reproductive, Gastro-Renal, and Urological Devices**
**510(k) Number** K130046