510(k) Summary of Safety and Effectiveness

Date Summary Prepared: 05/05/06

SEP 19 2006

Applicant:	Medical Products Division A Division of Specialty Manufacturers, Inc. 2410 Executive Drive Indianapolis, IN 46241
Phone:	(317) 241-1111
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Establishment Registration Number:	Medical Products Division will submit FDA forms 2891 and 2892 following 510(k) clearance.
Contact:	Thomas W. Copeland
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Prepared by:	Thomas Copeland, President Medical Products Division 2410 Executive Drive Indianapolis, IN 46241
Phone:	(317) 241-2457
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Device Information

Proprietary Name:	HierSpec Speculum
Common/Usual Name:	Disposable Vaginal Speculum
Classification Name:	Speculum, Vaginal, Nonmetal
Device Classification:	Class 2
Regulation Number:	21 CFR § 884.4530
Product Code:	HIB

Predicate Device

Device Name:	Kleenspec
Manufacturer:	Welch Allyn
510(k) Number	K941272

Indications For Use

The Hier-Spec vaginal speculum is a non-metal (Acrylic and Polycarbonate), hand held device used to open the vagina and provide access to the cervix for gynecological or obstetrical examinations and procedures.

SUBSTANTIAL EQUIVALENCE COMPARISON

CHARACTERISTIC	HierSpec Speculum	WelchAllyn Kleenspec® Disposable Vaginal Speculum
Intended Use and Indications for Use	The Hier-Spec vaginal speculum is a non-metal (Acrylic and Polycarbonate), hand held device used to open the vagina and provide access to the cervix for gynecological or obstetrical examinations and procedures.	Same
Design	When the device is in the closed position, for insertion into the vagina, the bow arms are in a horizontal position and the handles are open to approximately 45 degrees. After the device is inserted into the vagina, the handles are squeezed together and the connecting rail rotates the bow arms into a horizontal position to open the vaginal canal.	Duck Bill Design
Materials of Construction	Acrylic, Clear, PERSPEX CP- 82-F and GE Polycarbonate, Lexan 144R	Acrylic, Clear, PERSPEX CP- 82-F
Sterility	Not Sterile	Not Sterile
Biocompatibility	See Section 5, Page 5.1 and Welch Allyn Technical Information Bulletin 580092A page 5.2	Same
Mechanical Safety	Able to withstand the forces required for proper insertion, (with or without lubrication) and the compressive force exerted by normal female vaginal contractions.	Same
Anatomical Sites	Vaginal canal.	Same
Human Factors	Single handed use. Self-locks in open position.	Same
Compatibility with the environment	Disposable	Same
Compatibility with other devices	Compatible with various spatula, Cyto brushes, packing forceps, sound and tenaculum, Tischler Bioposy forceps, scrapers, swabs, and probes.	Same
Where used	Professional medical facilities or office / clinical examination rooms	Professional medical facilities or office / clinical examination rooms
Performance Standards	None	Same
Hand held and manually operated	Yes	Yes
Single Use	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 19 2006

Mr. Thomas W. Copeland
Division President
Specialty Manufacturers, Inc.
2410 Executive Drive
INDIANAPOLIS IN 46241

Re: K061339
Trade/Device Name: HierSpec Vaginal Speculum
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: August 28, 2006
Received: August 31, 2006

Dear Mr. Copeland:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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

2. Statement of Indications for Use

510(k) Number: K061339

Device Name: HierSpec Speculum

INTENDED USE AND INDICATIONS FOR USE

The Hier-Spec vaginal speculum is a non-metal (Acrylic and Polycarbonate), hand held device used to open the vagina and provide access to the cervix for gynecological or obstetrical examinations and procedures.

Carolyn P. Neuland for N.C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061339