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510(K) SUMMARY

Dynarex Vaginal Speculum 510(k) #: K052314

Submitter	Dynarex Corporation 10 Glenshaw Street Orangeburg, NY 10962 USA Phone: 845-365-8200 Fax: 845-365-8201
Contact Person	James Hurlman
Date of Summary	08-04-2005
Trade Name	Dynarex Vaginal Specula, 4900 Series (Models 4911-Small, 4912 – Medium, and 4913 – Large)
Common Name	Speculum, Vaginal, Non-Metal
Classification Name	Obstetric-Gynecologic Specialized Manual Instrument (21 CFR 884.4530)
Predicate Device	Dukal Vaginal Speculum 510(k) #: K020726
Intended Use	The Dynarex Vaginal Specula is used to expose the interior of the vagina.

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510(K) SUMMARY

Dynarex Vaginal Speculum 510(k) #: K052314

Description of Device:

The Dynarex vaginal speculum is a non-metal (polystyrene), non-lubricated, hand held device used to expose the interior of the vagina to facilitate visualization during gynecological and obstetrical procedures.

Technical Characteristics:

The Dynarex vaginal speculum has the same technological characteristics as, and is substantially equivalent to, the Dukal Vaginal Speculum, 510(k) #: K020726.

Table of Comparisons

Characteristic	*Dynarex Vaginal Speculum*	*Dukal Vaginal Speculum*
Indications for Use	This device is used to expose the interior of the vagina.	This device is used to expose the interior of the vagina.
Design	Injection Molded, clear plastic.	Injection Molded, clear plastic.
Materials	Polystyrene	Polystyrene
Performance	Hand operated, multi-position	Substantially Equivalent
Sterility	Non-Sterile	Non-Sterile
Mechanical Safety	Simple thumb adjustable lever action.	Substantially Equivalent
Lubrication	Non-Lubricated	Non-Lubricated
Packaging	Bulk Pack 10/Plastic Bag, and Individually wrapped.	Bulk Pack 10/Plastic Bag, and Individually wrapped.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2005

Mr. James Hurlman
Official Correspondent
Dynarex Corporation
10 Glenshaw Street
ORANGEBURG NY 10962

Re: K052314
Trade/Device Name: Dynarex Vaginal Specula, 4900 Series (Models 4911 - Small, 4912 - Medium and 4913 - Large
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: October 10, 2005
Received: October 12, 2005

Dear Mr. Hurlman:

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

K052314

Indications for Use

510(k) Number (if known): K052314

Device Name: Dynarex Vaginal Specula, 4900 Series (Models 4911-Small, 4912 – Medium, and 4913 – Large)

Indications For Use: This device is used to expose the interior of the vagina.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052314