K061306 p.1/2

Summary of 510(k) Information Premarket Notification, Section 510(k)	***CO-1000 Colposcope*** GYNEX Corporation, April 26, 2006

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. ***Device Name:*** ***CO-1000 Colposcope***
   Common Name: Colposcope
   Classification Name: Colposcope & Accessories

AUG - 7 2006

2. ***Establishment Name & Registration Number:***
   Name: Gynex Corporation
   Number: 3032109

Subpart B -- Obstetrical and Gynecological Diagnostic Devices

Sec. 884.1630 Colposcope. (a) *Identification.* A colposcope is a device designed to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy. This generic type of device may include a light source, cables, and component parts.

(b) *Classification.* Class II (performance standards).

Device Class: Class II
Classification Panel: Ob/Gyn Devices Panel
Product Code: 85 HEX

4. ***Equivalent Legally Marketed Device(s):***
The GYNEX ***CO-1000 Colposcope*** is substantially equivalent in terms of intended use, basic design, materials, method of manufacture, physical dimensions, and clinical utility as the following legally marketed device:

- DFV CPG Colposcope, K021854, DF Vasconcellos, SA

5. ***Device Description:***
The ***CO-1000 Colposcope*** is a precise optical instrument designed specially for the gynecologic examination. The Gynex brand colposcope can be used to view vaginal and cervical tissues using stereoscopic optics.

The Gynex CO-1000 Colposcope has detailed features that include wide field of view, long focal length, uniform illumination, adjustable brightness, ease of operation, and exceptional optics. It is an essential instrument for any gynecologic examination. The general features of the device are as follows:

- Eyepiece magnification: 12.5X
- Overall Magnification: 9X
- Focal length: 320mm
- Individually adjustable eyepieces
- Smooth adjustable controls for fine focus
- Universal Teflon ball joint gives you 360° easy motion for gross focus
- Built-in green filter for enhanced contrast
- Built-in rheostat
- Easy replacement of halogen light bulb
- Unit is completely assembled and ready for use once power is on

Indications for Use: The Gynex ***CO-1000 Colposcope*** is a device designed to permit viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. A Colposcope is used to diagnose and examine abnormalities of the vagina and cervix.

6. ***Applicant Name & Address:***
GYNEX Corporation
2789 – 152nd Avenue, N.E.
Redmond, Washington 98052
425.882.1179 - 425.895.0115

7. ***Company Contact:***
Mr. Stephen J. Sullivan, President
GYNEX Corporation
2799 – 152nd Avenue, N.E.
Redmond, Washington 98052
425.882.1179 - 425.895.0115
ssullivan@gynex.com

8. ***Submission Correspondent:***
Karen Cardiff
GYNEX Corporation
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Redmond, Washington 98052
425.882.1179 - 425.895.0115
kcardiff@gynex.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 7 2006

Ms. Karen Cardiff
Official Correspondent
Gynex Corporation
2789-152nd Avenue, N.E.
REDMOND WA 98052

Re: K061306
Trade/Device Name: CO-1000 Colposcope
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: April 26, 2006
Received: May 10, 2006

Dear Ms. Cardiff:

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

510(k) Number (if known): K061306

Device Name(s): ***CO-1000 Colposcope***

Intended Use:

The Gynex brand Colposcope is a device designed to permit viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. A Colposcope is used to diagnose and examine abnormalities of the vagina and cervix.

Prescription Use X OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061306