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Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	*Gynex Extended Reach Needle* GYNEX Corporation

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

1. Device Name:

Trade Name: ***Gynex Extended Reach Needle***
Common Name: Disposable Needle, disposable anesthetic needle
Classification Name: Obstetric anesthesia set & accessories

2. Establishment Name & Registration Number:

Name: GYNEX Corporation
Number: 3032109

3. Classification:

§ 884.5100 Obstetric anesthesia set. (a) Identification. An obstetric anesthesia set is an assembly of antiseptic solution, needles, needle guides, syringes, and other accessories, intended for use with an anesthetic drug. This device is used to administer regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during labor, delivery, or both. (b) Classification. Class II (performance standards).

4. Establishment Name & Registration Number:

Name: GYNEX Corporation
Number: 3032109

5. Classification:

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

6. Preamendments Device:

1. Pudendal and paracervical block anesthesia instruments, Gynecology, Obstetrics, V. Mueller, The Surgical Armamentarium, 1973., pp. 219

7. Equivalent Legally Marketed Device(s):

1. Potocky Needle - Disposable Injection Needle, K910252, Cooper Surgical.

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8. *Device Description:*

The ***Gynex Extended Reach Needles*** are made of 302 instrument grade stainless steel. There are two styles each being 27 gauge and 90mm in length. One is equipped with a standard Leuer lock type hub and the other has a threaded hub. Both are disposable. As is typical for this type of anesthetic needle, the shaft of the needle is dual diameter. That is, the shaft of the needle from the hub to within 5mm of the tip a is larger diameter. This allows for easy estimation of insertion depth during anesthetic administration and prevents over-insertion of needle into deeper tissue levels or spaces.

9. *Applicant Name & Address:*

GYNEX Corporation
16700 NE 79th St., Suite 204
Redmond, WA 98052

10. *Company Contact:*

Mr. Steve Angelo, President
GYNEX Corporation
16700 NE 79th St., Suite 204
Redmond, WA 98052
425.882.1179 * 425.895.0115 - fax

11. *Submission Correspondent:*

Mr. David W. Schlerf
Buckman Company, Inc.
1000 Burnett Av., Suite 450
Concord, CA 94520
510.356.2640 - 510.356.2654 - fax

12. *Comparison Table:*

FEATURE	Gynex Extended Reach Needle	Pudendal/Paracervical Needle & Potocky Needle	SE?
Indications for Use(s):	Administer Paracervical pudendal anesthetic	Administer Paracervical pudendal anesthetic	YES
Design:	Leuer lock & threaded hub	Leuer lock	Yes
Sterilization Method:	Radiation - Supplied sterile - disposable	Steam Autoclave - reusable Potocky -Supplied sterile - disposable	NO& YES
Sizes:	90mm w/ 5mm 27 gauge tip	6-8 inches - 20-25 gauge Potocky - 90mm, 27 gauge	YES
Material:	302 Stainless steel	302 Stainless Steel	YES
Country of Origin::	Asia - Germany	Germany Potocky - Asia - Germany	YES
Manufacturer:	Gynex Corporation	V. Mueller, Cooper Surgical	YES
Product Code:	84HEE	84HEE	Yes
K - Number:	Pending	Preamendment & K910252 respectively	YES

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13. *Voluntary Standards:*

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, GYNEX Corporation. Standard Operating Procedures (SOP), vendor certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

14. *Storage, Packaging & Sterilization Information:*

The ***Gynex Iris/Angle Extended Reach Needles*** are supplied sterile and non-pyrogenic.

All needles are individually packaged & labeled and supplied in multi-unit packages and boxes for ease in shipping and storage. All packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. Any shipping damaged product may not be sterile and should be returned promptly. Product for use in the operating room must be processed, opened, handled and placed into use following accepted operating room sterile technique.

Sterility Assurance Level (SAL) is at least 10^{-6}. A minimum of 2.5 M/rad radiation exposure is utilized. The product is dosemetry released. The product is also non-pyrogenic. Vendor certification and secondary sampling is performed and documented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 1998

Gynex Corporation
c/o Mr. David Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

Re: K980238
GYNEX Extended Reach Needle
Dated: June 20, 1998
Received: August 4, 1998
Regulatory Class: II
21 CFR 884.5100/Procode: 85 HEE

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980238

Device Name(s):

GYNEX Extended Reach Needles

Intended Use:

1. ***Injection and administration of anesthetic regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during labor, delivery, or both.***

2. ***Injection and administration of anesthetic regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during minor surgical procedures.***

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Nathing
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980238

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)