

<genX> international, Inc. 510(K) Premarket Notification

510K Summary

K991264

a) **DEVICE NAME**

Proprietary Name: <genX> Single Lumen Sideport Needle

Classification Name: Assisted Reproduction Needle

b) **ESTABLISHMENT REGISTRATION No.: 9003605**

<genX> international, Inc.
170 Fort Path Road
Madison, CT 06443
Tel: 203-245-4901
Fax: 203-245-4994

Contact Individual:
Michael D. Cecchi
President

c) **CLASSIFICATION: Class II**

Assisted reproduction needles

Product: <genX> Single Lumen Needle with Sideport

Procode: 85 MQE

CFR#: 884.6100

d) **PERFORMANCE STANDARDS**

Performance Standards under Section 514 of the ACT have not been developed for this device. However, Special controls have been identified by the FDA to provide reasonable assurance of safety and effectiveness of the device in assisted reproductive procedures.

e) **PROPOSED LABELS, LABELING, AND ADVERTISING**

The proposed labeling and instruction material is included in this package in the appropriate section.

f) **DESCRIPTION**

The <genX> Single Lumen Sideport Needle is intended to obtain gametes from the body. The catalog number is GNSP-732.

The basic design is a single stainless steel needle tubing of 32 cm in exposed length, with a grounded point. It is attached to a hub of polycarbonate designed especially for this purpose. The outer diameter of the outer needle tube maybe 16 or 17gauge, 17 being more desirable.

Attached to the hub are two lengths of tubing. One is attached to the rear of the needles, which allows the oocytes to be aspirated into a collection test tube, and the second length is attached to the flush port on the side. This second port is

attached to a syringe, which allows the operator to inject media into the follicle to allow "flushing"

g) SUBSTANTIALLY EQUIVALENT

The Single Lumen Sideport Needle is substantially equivalent to several products currently marketed in the US. See the appropriate section for the comparisons.
(Section 2)

h) STERILIZATION PROCEDURES AND FACILITIES

All needles manufactured, will be Gamma Irradiated by and according to the guidelines in place.

Dosage: 2.5 Mrad

Sterility Assurance Level (SAL): of $(10 \text{ to the } -6)$

After sterilization the contractor will issue a "Certificate of Sterilization".

Validation assurance is in accordance with ANSI / AAMI / ISO 11137-1994 Standards.

See Section 11.0



SEP 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael D. Cecchi
President
<genX> International, Inc.
170 Fort Path Road, Unit 14
Madison, CT 06443

Re: K991264
<genX> Single Lumen Sideport Needle
Dated: June 10, 1999
Received: June 22, 1999
Regulatory Class: II
21 CFR §884.6100/Procode: 85 MQE

Dear Mr. Cecchi:

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

<genX> international, Inc. 510(K) Premarket Notification

Response #2

Re: K991264
Single Lumen Sideport Needle

INDICATIONS FOR USE

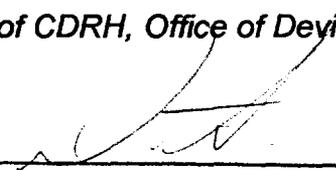
510 (k) Number (if known) _____ K991264 _____

Device Names: <genX> Single Lumen Sideport Needle
Indication for Use:

“Used to obtain oocytes from the body”

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991264

Prescription Use X or Over-the Counter Use _____