

SEP 9 1999

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

1.0

510K Summary

K991266

- a) **Device Name: Assisted Reproduction Accessories**
Proprietary Name: <genX> Embryo Transfer Catheter
CC Glider™
- b) **Establishment Registration Number: 9003605**
<genX> international, Inc.
170 Fort Path Road
Madison, CT 06443
Tel: 203-245-4901
Fax: 203-245-4994
E-mail: genxintl@aol.com
- Contact Individual:**
Michael D. Cecchi
President
- c) **Classification: Class II**
Assisted Reproductive Catheter
Product: <genX> Embryo Transfer Catheter
Procode: 85 MQF
CFR#: 884.6110
- d) **Performance Standards/Special Controls:**
Food and Drug Administration has developed no Performance standard under section 514 of the Act for this device. However, certain special Controls have been identified in order to provide reasonable assurance of the safety and effectiveness of the device used in assisted reproduction procedures.
- e) **Proposed Label, Promotion, and Advertising**
Draft labels and promotion material is included in the appropriate section of this application.
- f) **Statement of Substantially Equivalence**
<genX> international Inc. considers this catheter to be substantially equivalent in design and intended use to a number of predicated catheters legally marketed in United States. These catheters are discussed in the appropriate section.
- g) **Device Description, Intended Use and Direction for Use**

Product Design

The <genX> Embryo Transfer Catheter There will be two (2) catheters made from the same basic design and materials in order to accommodate the market needs for standard and for more difficult transfers. The catalog numbers of the two models are GECT-100 and GETC-200.

The basic design of the two models will consist of an inner catheter of 5 French O.D. and an outer catheter of 9 French tapering to 7 French O.D. with a one centimeter marking on the distal tip. The inner catheter has a support/holding outer sleeve extending from the handle end along the catheter for 5 cm.

The inner catheter will extend approximately 5 cm out of the outer catheter when fully engaged for the standard model and 3 cm for the difficult transfer model.

The materials are of implant grade medical polymers, to be wrapped for single use.

h) **Sterilization Procedures and Facilities**

There will be three variations of the catheter made to suit the market needs. All will be of a polymer that may be gamma radiated or E-Beamed. We consider these to be equivalent in the method and results, and may use both in the process.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Michael D. Cecchi
President
<genX> International, Inc.
170 Fort Path Road, Unit 14
Madison, CT 06443Re: K991266
<genX> Embryo Transfer Catheter
CC Glider™
Dated: June 10, 1999
Received: June 23, 1999
Regulatory Class: II
21 CFR §884.6110/Procode: 85 MQF

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

