FEB 1 4 2000

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

510(K) Summary

K993884

a) DEVICE NAME
Proprietary Name: <genX> Microtools

Classification Name: Assisted Reproduction Microtools

b) Submitted by:
<genX International, inc.
170 Fort path Rd.
Madison, CT 06443

ESTABLISHMENT REGISTRATION No.: 9003605

Tel: 203-245-4901
Fax: 203-245-4994

Contact Individual:
Michael D. Cecchi
President

c) CLASSIFICATION: Class II
Assisted Reproductive Microtools
Product:
<genX> ICSI Microtools
<genX> Holding Micro Pipettes
<genX> ICSI Micro Pipettes

Procode: 85 MQJ
CFR#: 884.6150

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) INDICATION FOR USE AND DESCRIPTION
The <genX> ICSI Microtools are intended Used to micromanipulate, hold, or transfer oocytes or embryos for assisted hatching, intsacytoplasmic sperm injection (ICSI) or

other assisted reproduction methods. The catalog numbers are GIPR-025 for Rigid and GARF-025 for flexible

The basic design is a borosilicate glass tube, drawn to form a microinjection and/or microholding holding instrument. Each is angled towards the tip end to allow the instrument to be parallel to the surface of the dish.

By apply suction the holding pipette is able to hold the cell in place, and the micro injection tool may pull cells into the hollow middle and then inject these cells into a larger cell mass.

g) Sterilization Procedures and Facilities

The tools are individually packaged and then gamma radiated.
All tools manufactured, will be Gamma Radiation by and according to the guidelines in place.

Dosage level: 28kGy +/- 15%

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

After sterilization a " Certificate of Sterilization" will be issued by the contractor.

h) Statement of Substantially Equivalence

<genX> international Inc., considers <genX>ICSI Microttools to be substantially equivalent in design and intended use to a number of predicated ICSI Microttols legally marketed in United States. These tools are manufactured and distributed by Humagen and Cook IVF.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2000

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

Re: K993884
<genX> ICSI Microtools
Dated: November 14, 1999
Received: November 16, 1999
Regulatory Class: II
21 CFR §884.6150/Procode: 85 MQJ

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

INDICATIONS FOR USE

510 (k) Number (if known) K993884

Device Names: <genX> ICSI Microtools

Indication for Use:

"Used to micromanipulate, hold, or transfer gametes or embryos for assisted hatching, intsacytoplasmic sperm injection (ICSI) or other assisted reproduction methods"

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the Counter Use ____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993884

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