DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2008

Mr. Michael D. Cecchi
President
<GenX> International, Inc.
393 Soundview Road
GUILFORD CT 06443

Re: K080395
Trade/Devices Name: See enclosed list
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Dated: July 19, 2008
Received: July 25, 2008

Dear Mr. Cecchi:

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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Trade Names of Devices Cleared in <GenX> International, Inc. Submission K080395

All of the devices below are assisted reproductive labware devices (884.6160, product code MQL, Class II)

- SunIVF Universal Dish
- SunIVF Micromanipulation Dish
- SunIVF ICSI Dish
- SunIVF Freezing Dish 1
- SunIVF Freezing Dish 2
- SunIVF Vitrification Dish
- SunIVF Rotational Dish
- SunIVF General Flat Dish – 35 X 10 mm
- SunIVF General Flat Dish – 60 X 15 mm
- SunIVF General Flat Dish – 90 X 17 mm

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF Universal™ Dish

Indication for Use:

The SunIVF Universal™ Dish is intended to be used to hold human sperm, oocytes, and embryos during their manipulation and culture in in-vitro procedures of assisted human reproduction, including washing, handling, conventional in-vitro fertilization, fertilization by intracytoplasmic sperm injection, assisted hatching, biopsy, and cryopreservation.

(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 and Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF Micromanipulation™ Dish

Indication for Use:

The SunIVF Micromanipulation™ Dish is intended to be used to hold human oocytes and embryos during in-vitro procedures of assisted human reproduction, including fertilization by intracytoplasmic sperm injection, assisted hatching, and biopsy.

(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 and Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF ICSI™ Dish

Indication for Use:

The SunIVF ICSI™ Dish is intended to be used to hold human oocytes and sperm during the procedure of fertilization by intracytoplasmic sperm injection.

(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 and Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF Freezing Dish 1

Indication for Use:

The SunIVF Freezing Dish 1 is intended to be used to hold human oocytes and embryos during the procedures of cryopreservation.

(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 and
Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF Freezing Dish 2

Indication for Use:

The SunIVF Freezing Dish 2 is intended to be used to hold human oocytes and embryos during the procedures of cryopreservation.

(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 and Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF Vitrification Dish

Indication for Use:

The SunIVF Vitrification Dish is intended to be used to hold human oocytes and embryos during the procedures of vitrification.

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Prescription Use X or Over-the Counter Use _____

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF Rotational Dish

Indication for Use:

The SunIVF Rotational Dish is intended to be used to hold human oocytes and embryos during handling and culture.

(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 and Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF General Flat Dish – 35 X 10 mm

Indication for Use:

The SunIVF General Flat Dish – 35 X 10 mm is intended to be used for washing and handling of human oocytes and embryos.

(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 _____

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF General Flat Dish – 60 X 15 mm

Indication for Use:

The SunIVF General Flat Dish – 60 X 15 mm is intended to be used for washing and handling of human oocytes and embryos.

(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 and
Radiological Devices
510(k) Number K080395

INDICATIONS FOR USE

510 (k) Number (if known): K080395

Device Names: SunIVF General Flat Dish – 90 X 17 mm

Indication for Use:

The SunIVF General Flat Dish – 90 X 17 mm is intended to be used for washing and handling of human oocytes and embryos.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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