MAR 1 2 2007

5. 510(k) Summary

RESEARCH INSTRUMENTS LIMITED

Bickland Industrial Park, Falmouth, Cornwall TR11 4TA, U.K.
Tel: 01326 372753 [International +44 1326 372 753]
Fax: 01326 378783 [International +44 1326 378 783]
e-mail: technical@research-instruments.com
website: www.research-instruments.com

Date prepared [21CFR807.92(a)(1)]

March 20, 2006

Submitter's information [21CFR807.92(a)(1)]

Company Name: Research Instruments LTD.
Registration number: 9617095
Address: Bickland Water Industrial Park
Falmouth
Cornwall,
United Kingdom Tr 11 4ta
Telephone: +44 (0) 1326 372 753
Fax: +44 (0) 1326 378 783
Contact person: David Lansdowne
Contact title: Technical Director
Contact email: david@research-instruments.com

Trade Name, Common Name, Classification [21CFR807.92(a)(2)]

Trade Name: Saturn 3 Laser System
Common Name: Assisted Reproduction Laser System
Device Class: [redacted]II
Regulation Number: 21CFR884.6200
Product Code: MRX

Identification of Predicate Device [21CFR807.92(a)(3)]

Substantial Equivalence to Hamilton Thorne Zilos-tk (K050768)

Description of the Device [21CFR807.92(a)(4)]

The Saturn 3 Laser System is a device that images, targets, and controls the power and pulse duration of a laser beam used to ablate a small

tangential hole in, or to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

Intended Use [21CFR807.92(a)(5)]

The Saturn 3 Laser System is to be used to drill a small tangential hole in, or to thin, the zona pellucida of the embryo in selected *in vitro* fertilization (IVF) patients with otherwise poor prognosis for successful pregnancy outcome, such as: Advanced maternal age, Prior failed IVF, Cryopreserved embryos, Abnormal zona pellucida morphology.

Technological Characteristics [21CFR807.92(a)(6)]

Features Compared and found equivalent

Laser Wavelength
Laser Power
Pulse time range
Laser classification
Number of preset pulse times
Presets user definable
Pilot laser for alignment checking
Pilot laser power,
Pilot laser classification
Custom objective to focus infrared parfocal to visible
Objective magnification
Objective Numerical Aperture
Computer generated target
Hole size indicator
Still image recording
Video image recording
Measurement tools
Report generation

Non-clinical Testing [21CFR807.92(b)(1)]

Measurement of laser power and pulse lengths demonstrates that the Saturn 3 delivers pulse energies comparable to the predicate. With the alignment procedure correctly performed the coalignment of the target and the ablated hole is within 1µm. This is also comparable to the predicate.

Clinical Testing [21CFR807.92(b)(2)]

A recent study has shown that the Saturn 3 Laser System is safe for use on human embryos.

Reproductive BioMedicine Online 2005 Vol. 11, No. 6. 697–710

"Comparison of the effects of zona drilling by non-contact infrared laser or acid Tyrode's on the development of human biopsied embryos as revealed by blastomere viability, cytoskeletal analysis and molecular cytogenetics" K Chatzimeletiou et al

Conclusions [21CFR807.92(b)(3)]

The Research Instruments Saturn 3 Laser System is substantially equivalent to the Hamilton Thorne Zilos-tk based on the following:

(a) The pulse energies delivered by the two systems are comparable, and create similarly sized holes in the embryo zona pellucida.

(b) Clinical trials show that both systems are safe for use on human embryos, when operated in the prescribed manner.

(c) Both systems are operated in a similar way by the user.

The Research Instruments Saturn 3 Laser System has the same intended use as the predicate, and has performance and method of operation substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Research Instruments Ltd.
c/o Ms. Grace Holland
Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

MAR 12 2007

Re: K060764
Trade/Device Name: Saturn 3 Laser System
Regulation Number: 21 CFR §884.6200
Regulation Name: Assisted reproduction laser system
Regulatory Class: II
Product Code: MRX
Dated: January 9, 2007
Received: January 11, 2007

Dear Ms. Holland:

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 (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 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 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" (21 CFR 807.97). 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 (301) 443-6597 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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K060764

Device Name: Saturn 3 Laser System

Indications for Use:

The Saturn 3 Laser System is to be used to drill a small tangential hole in, or to thin, the zona pellucida of the embryo in selected *in vitro* fertilization (IVF) patients with otherwise poor prognosis for successful pregnancy outcome, such as:

- Advanced maternal age
- Prior failed IVF
- Cryopreserved embryos
- Abnormal zona pellucida morphology

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060764