RESEARCH INSTRUMENTS LIMITED

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

## 5. 510(k) Summary

K083208

AUG 2 5 2009

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

October 22nd, 2008

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

Company Name: Research Instruments Ltd.
Registration Number: 9617095
Address: Bickland Water Industrial Park
Falmouth, Cornwall TR11 4TA
United Kingdom
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 Active Laser System
Common Name: Assisted Reproduction Laser System
Device Class: 11
Regulation Number: 21CFR884.6200
Product code: MRX

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

Substantial Equivalence to Research Instruments Ltd. Saturn 3 Laser System Predicate 510(k) No. K060764

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

The Saturn Active Laser System is a device that images, targets, and controls the power and pulse duration of a laser beam to ablate a small tangential hole in, or thin, the Zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

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

The Saturn Active 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.

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

Technological Characteristics [21CFR807.92(a)(5]

***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

***Features Compared and not found equivalent***

Motor module to position laser

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 co-alignment of the target and the ablated hole is within 1µm. this is also comparable to the predicate.

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

To our knowledge no clinical trials have been performed with Saturn Active.

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

The Research Instruments Saturn Active Laser System is substantially equivalent to the Research-Instruments Saturn 3 Laser System based on the following:

The two systems share the majority of components. The control unit, laser sources, fibre optics, collimation lens, dichroic mirror and objective are the same. The only significant difference between the two systems is the addition of a motorised beam steering module in Saturn Active.

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

The pulse energies delivered by the two systems are the same, and create the same sized holes in the embryo zona pellucida.

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

The additional components and software have been validated by non-clinical testing.

The Research Instruments Saturn Active 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 Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. David Lansdowne
Technical Director
Research Instruments Limited
Bickland Industrial Park
Falmouth, Cornwall
TR114TA
UNITED KINGDOM

AUG 2 5 2009

Re: K083208
Trade/Device Name: Saturn Active Laser System
Regulation Number: 21 CFR §884.6200
Regulation Name: Assisted reproduction laser system
Regulatory Class: II
Product Code: MRX
Dated: August 10, 2009
Received: August 12, 2009

Dear Mr. Lansdowne:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

RESEARCH INSTRUMENTS LIMITED

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

## 4 Indications for Use

510(k) Number (if known): K083208

Device Name: Saturn Active Laser System

Indications for Use:

Saturn Active is a 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 YES (Part 21 CFR 801 Subpart D) AND/OR Over-The Counter Use NO (Part 21 CFR 801 Subpart C)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083208