510(k) Pre-Market Notification
Summary Report

DEC 15 2006

Submitted By:	Minitube of America, Inc. 411 B Venture Ct. PO Box 930187 Verona WI. 53593
Contact Person:	Frederick Rikkers Rikkers Law 419 Venture Court, P.O. Box 930555 Verona, WI 53593
Date Prepared:	July 18, 2006
Trade Name:	OCTAX Laser Shot™ System
Common Name:	OCTAX Laser
Device Classification Name:	Assisted Reproduction Laser Systems MRX - CFR # 884.6200
Special Controls Document:	"Class II Special Controls Guidance Document: Assisted Reproduction Laser System" issued on December 28th, 2004
Predicate Device:	Hamilton Thorne Zona Infrared Laser Optical System (Zilos), 510(k) number: K040045.

Description of Device:

The OCTAX Laser Shot™ laser device is a microscope based micromanipulation tool for use in ART in *In Vitro Fertilization* laboratories. The device uses a 1.48 µm infrared diode laser and has been supplemented with a miniature digital video camera and computer software allowing precise laser control, image storage and database and analysis functions.

The OCTAX Laser Shot™, introduced to the market in October 2000, is the 2nd generation infrared diode laser developed at OCTAX Microscience GmbH by a team lead by Dr. Klaus Rink, based on extensive experience with the first commercial 1.48 µm infrared diode laser (Fertilase), introduced to the market 1996, director research and development at that time: Dr. Klaus Rink (Physicist).

Statement of Indicated Use

The OCTAX Laser Shot™ is a laser system for microsurgery on a cellular level, which works on a semiconductor basis. It is intended to be used to ablate a small tangential hole in the zona pellucida (assisted hatching) to be performed immediately prior to transfer on day 2 or day 3 in selected in vitro fertilization (IVF) patients with otherwise poor prognosis for successful pregnancy outcome, such as those with advanced maternal age, prior failed IVF, cyropreserved embryos, or abnormal zona pellucida characteristics. For safety reasons, the system should only be used if more than one embryo is available for transfer.

Technological Characteristics

The OCTAX Laser Shot™ system is to be compared with the following predicate device: Hamilton Thorne Zona Infrared Laser Optical System (Zilos), 510(k) number: K040045, based upon the criteria provided by the FDA. The technological and performance characteristics of the OCTAX Laser Shot™ system are substantially equivalent to this predicate device and are detailed in the Substantial Equivalence Performance section of the 510(k) submission document. The substantial equivalence applies both on a technological level, as well as preclinical/clinical data and operating characteristics.

Testing Performed for Safety, Accuracy and Software Validation

The OCTAX Laser Shot™ system, and its predecessor, the Fertilase system have been used throughout the world for over 10 years. Its efficacy, safety and accuracy has been tested and retested over the years and noted in many publications. Also, the software used in the OCTAX Laser Shot™ system has been validated on numerous occasions.

Substantial Equivalence Performance

	Similarities	Differences
Technological and scientific history	Both devices implement the same technological principle and are based on the same scientific background as published in the literature.	In addition to sharing the common history, the OCTAX Laser Shot™ system is more close to the scientific background of the technology due to the fact that its development was lead by Dr. Klaus Rink, who was also a member of the team of researchers who established this scientific background.
Indications for use	The indications for use regarding zona pellucida drilling are identical for both devices.	The indication for zona thinning of the predicate device has not been included in the indications for use of the OCTAX Laser Shot™ system to lower the requirements for documentation of the device and of relevant clinical studies in this extent. Additionally, as a result of a more conservative approach to potential hazards of laser assisted hatching, an additional requirement of the availability of more than one embryo for transfer was added.
Target Population	Identical	
Laser type	Identical (infrared diode laser)	
Wavelength	Identical (1.48 µm)	
Laser interaction with target	Identical interaction process	
Objective	Objective with high infrared transmission	The OCTAX Laser Shot™ system includes an objective with a 40x magnification, while the objective of the predicate device has a 50x magnification.
Laser path	Functionally identical - from the laser diode passing by a semi-transparent mirror into (and focused by) the objective onto the	While the predicate device integrates objective, semitransparent mirror and laser diode into a single enclosure, the OCTAX Laser Shot™

	specimen	system consists of a separate objective, semitransparent mirror block and laser unit. Apart from the mechanical aspect there is no functional difference with respect to the laser beam path.
Beam information	Identical (radially symmetric, with Gaussian beam profile)	
Power levels	Same order of magnitude	While predicate device operates with a power in focus in air of up to 300 mW, the OCTAX Laser Shot™ has a power in focus in air of 90-130 mW (which is more close to the power levels used in the fundamental safety studies published in the literature).
Laser pulse duration	Resulting in same order of magnitude energy per laser pulse	While the predicate device relies on shorter pulses (0.1-2ms) at higher power levels, the OCTAX Laser Shot™ uses slightly longer pulses (0.1-10ms) while the total energy per laser pulse remains lower compared to the predicate device, while achieving similar ablation performance (size of ablations)
Laser pulse repetition	Identical (single pulses without repetition)	
Laser targeting	Identical (through crosshair overlay superimposed to a live video display of the microscope image implemented by software on a PC).	
Materials	Both use standard materials common to microscopy equipment. The materials in use are of no concern as the devices do not come into direct (physical) contact with the target.	
Performance	Both devices have substantially similar performance due to the substantial similarity of the laser beam characteristics.	
Sterility	Both devices present no concern regarding sterility as they do not come into direct (physical) contact with the target	
Biocompatibility	Not applicable, see Sterility.	
Mechanical Safety	The mechanical safety aspects are similar for both devices.	The difference in design relating to the specific place where the laser is introduced into the microscope beam path is addressed with respect to its safety implications in Exhibit A.
Chemical Safety	Not applicable	
Anatomical Sites	Not applicable	
Human Factors	As the design and the use of the device is substantially similar, the same human factors apply.	
Energy Used and/or Delivered	The amount of laser energy delivered in a treatment procedure is similar.	The OCTAX Laser Shot™ system can achieve similar ablation performance (size of ablations) with a lower laser beam power in focus and a lower total delivered energy.
Compatibility with Environment and Other Devices	Relevant compatibility aspects consist of compatibility with electrical standards and compatibility with listed microscopes. Both devices satisfy the similar/identical requirements.	
Where Used	Both devices are used in IVF routine and are mounted on compatible inverted	

	microscopes.	
Preclinical studies	Identical (reference of fundamental research journal articles published in the literature)	
Clinical studies	Similar (reference of relevant journal articles published in the literature)	
Electrical Safety	Compliance with relevant electrical safety standards, IEC 60101-1, IEC 61010-1 and EMC compliance according to IEC 61326	
Radiation Safety	Compliance with relevant eye safety regulations according to IEC EN 60825-1	According to IEC EN 60825-1, the OCTAX Laser Shot™ system is a class 1M device. The Hamilton Thorne Zilos system is a class 1 device. As stated in Exhibit A, both class 1 and class 1M imply sufficient safety for the use of the device.

Conclusion

The non-clinical and clinical data for the OCTAX Laser Shot™ system, as reported in the Substantial Equivalence Performance section above, shows that the device is as safe, as effective, and performs as well or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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DEC 15 2006

Re: K062524
Trade/Device Name: OCTAX Laser Shot System
Regulation Number: 21 CFR 884.6200
Regulation Name: Assisted reproduction laser system
Regulatory Class: II
Product Code: MRX
Dated: November 2, 2006
Received: November 3, 2006

Dear Mr. Rikkers:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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

Indications for Use

510(k) Number (if known): K062524

Device Name: OCTAX Laser Shot™

Indications For Use: The OCTAX Laser Shot™ is a laser system for microsurgery on a cellular level, which works on a semiconductor basis. It is intended to be used to ablate a small tangential hole in the zona pellucida (assisted hatching) to be performed immediately prior to transfer on day 2 or day 3 in selected in vitro fertilization (IVF) patients with otherwise poor prognosis for successful pregnancy outcome, such as those with advanced maternal age, prior failed IVF, cryopreserved embryos, or abnormal zona pellucida characteristics. For safety reasons, the system should only be used if more than one embryo is available for transfer.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062524