A DNA Technology Company
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5. 510(k) Summary

APR 24 2007

Owner:	**Hamilton Thorne Biosciences**
Address:	**100 Cummings center suite 465E** **Beverly, MA 01915** 978-921-2050 tel 978-921-0250 fax
Contact person:	Diarmaid H. Douglas-Hamilton
Date	November 30 2006
Trade Name:	ZILOS-tk,
Common name:	Laser drill.
Classification Name	Assisted reproduction laser system (21 CFR 884.6200, code MRX)

Equivalent legally marketed device: ZILOS-tk

The ZILOS-tk uses an infra-red [IR] laser beam [of wavelength in the range $1450 < \lambda < 1480$ nm] to locally heat a small spot on the embryo zona pellucida. The IR beam is projected through the microscope objective in a direction opposite to the image light, so that it focuses on the embryo. This epi-irradiating IR beam is confocal with the visible beam, and the user adjusts the line-up of the target to treat the exact region of the zona desired. The beam power is typically 300 mW and the beam is pulsed on for typically 500 μsec or less, with a 40x objective. The thermal effect of the beam is to liquefy the zona pellucida in a small region surrounding the focal point, and thereby provide access to the embryo itself,. The hole drilled in this manner can be used either to aid hatching or for biopsy cell extraction. The assembled ZILOS-tk laser system is the same length as a microscope objective and can be fitted on to the turret of any inverted microscope. It can be controlled by a desktop or laptop computer.

The intended use of the ZILOS-tk includes laser assisted hatching [LAH] and laser-assisted blastomere or trophectoderm biopsy [LAB]. LAH is applied to in vitro treatment embryos from older women or embryos that have been frozen, in order to maximize their chances of implantation and pregnancy, and has been approved for marketing [K040045]. On the other hand LAB is used for providing specimen blastomeres (or trophectoderm cells) for pre-implantation genetic diagnosis [PGD]. PGD is indicated when the parents have dominant or recessive forms of genetic diseases, as happens in specific populations, for example in people of Ashkenazim ancestry [Tay-Sachs] or in Mediterranean littoral populations [β-thalasssemeia]. Laser-assisted PGD has allowed selection of embryos completely free of certain hereditary diseases such as β-thalassemia, with consequential

successful delivery of a healthy infant. The Indication for Use of the ZILOS-tk is extended in this submission to include LAB. Penetration of the zona pellucida for the purpose of biopsy is basically the same as penetration for laser hatching. The range of hole diameters used for laser hatching is closely similar to that used for LAB. Since the device is the same and its properties and pulse lengths are not changed from its LAH application, the actual effect of the laser is the same in both cases, and the safety and effectiveness of the ZILOS-tk are the same in both cases.

Technological characteristics. The ZILOS-tk in this Submission is identical to the ZILOS-tk already approved for marketing in its physical properties and in its computer control software. The laser, objective, computer, software, microscope type, laser controller, pulse power, pulse duration and firing switch are all identical to the predicate ZILOS-tk. The devices are not changed and all technical aspects are the same.

Performance Data. The ZILOS-tk has been applied to laser biopsy and PGD in numerous laboratories throughout the world. References to this work are attached. Both blastomere biopsy at the 3-day stage, and trophectoderm biopsy at the 5-day, have been used. PGD following LAB has been successfully employed to prevent hereditary disease in offspring. At different sites a total of more than six hundred 3-day embryos has been treated with lasers to assist biopsy, and no reports of embryo damage have been found. ZILOS-tk assisted trophectoderm biopsy has been reported used on more than 1000 embryos, all of which survived the procedure.

Safety and Effectiveness. In the drilling application, the evidence from the field use of the ZILOS-tk is that the instrument performs exactly as well as the predicate device, since no significant changes have been made in its design, software or operation. There is no increase in risk and no change in effectiveness. We conclude that the application of the ZILOS-tk to LAB entails no increased danger or potential problem from the approved application to LAH.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Diarmaid H. Douglas-Hamilton
Sr. VP Research & Development
Hamilton Thorne Biosciences
100 Cummings Center, Suite 465E
BEVERLY MA 01915-6143

APR 24 2007

Re: K063636
Trade/Device Name: The Hamilton Thorne Infrared Laser Optical System
Regulation Number: 21 CFR 884.6200
Regulation Name: Assisted reproduction laser system
Regulatory Class: II
Product Code: MRX
Dated: March 19, 2007
Received: March 20, 2007

Dear Mr. Hamilton:

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): K063636

Device Name: The Hamilton Thorne Infrared Laser Optical System [Zilos-tk] Diode Laser

Indications For Use: This system is intended 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 procedures, cryopreserved embryos, or abnormal zona pellucida morphology, and in IVF patients undergoing PGD to avoid genetic disease or aneuploidy.

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 IF 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 K063636