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K120055
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Innovations to Rely On

HAMILTON THORNE

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April 5 2012

510(k) Summary for
ZILOS-tk and LYKOS

A. Sponsor

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B. Contact Name

Primary Contact: Diarmaid Douglas-Hamilton
Secondary Contact : Sudha Thimmaraju

C. Device Name

ZILOS-tk [Zona Infrared Laser Optical System – Turn Key]
LYKOS

D. Product Code

ZILOS-tk: Assisted Reproduction Laser System, 884.6200: Product Code MRX
LYKOS: Assisted Reproduction Laser System, 884.6200: Product Code MRX

E. Predicate Device(s)

Hamilton Thorne Infrared Laser Optical system (Zilos-tk) (K063636)
Research Instruments Saturn 3 laser system (K060764)

F. 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.

G. Device Description

There are two configurations offered. The ZILOS-tk has already been cleared [510(k) K063636], and the LYKOS is a new design version. The assembled Infrared Laser Optical System (ZILOS-tk) is the same length as a microscope 40x objective and can be fitted onto the turret of any inverted microscope. In addition a slightly different configuration is offered (Infrared Laser Optical System LYKOS system) in which the laser is integrated within a microscope 40X objective. As with Zilos-tk, it mounts on the turret of any inverted microscope and has the same intended use.

The **ZILOS-tk** and **LYKOS** are used in the reproductive laboratory for cutting a hatching hole in the zona pellucida (ZP) of embryos. The hole cut in the zona pellucida can be used to extract blastomere(s) for PGD. The devices can also be used to cut a herniated trophectoderm-cell biopsy from the embryo.

The devices use 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. 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.

Weakening or breaking the junction between the trophectoderm cells so that they can be aspirated into the biopsy micropipette is also facilitated by using multiple pulses. Therefore a software change was made to add a multi-pulse mode which will allow for sequential multiple-pulse firing of the laser by a single footswitch press.

H. Substantial Equivalence

The Zilos-tk and the Lykos are substantially equivalent to the Hamilton Thorne Infrared Optical System (Zilos-tk) cleared via 510(k) K063636. These devices have the same Indication for Use and the same technological characteristics. Modifications to the Zilos-tk were detailed in this submission and evidence presented shows these devices are substantially equivalent. The modified ZILOS-tk and the LYKOS contain the RED-i visible directional beam for aiming the laser, which is substantially equivalent to the pilot laser for alignment checking of the Research Instruments Saturn 3 (K060764)

A comparison table is given below summarizing the features equivalent to the Predicates.

Features compared and Found Equivalent for Zilos-tk and Lykos Devices	Predicate 1 Zilos-tk (K063636)	Predicate 2 Saturn 3 Laser System (K060764)
Laser Wavelength	X	
Laser Power	X	

Features compared and Found Equivalent for Zilos-tk and Lykos Devices	Predicate 1 Zilos-tk (K063636)	Predicate 2 Saturn 3 Laser System (K060764)
Laser Pulse Duration	X	
Laser Classification	X	
Laser Preset Pulse Durations	X	
RED-i beam for laser beam target alignment		X
Objective Magnification	X	
Objective Focal Length	X	
Computer Generated Target	X	
Isotherms at Laser Target	X	
Image Capture	X	
Video Image Recording	X	
Measurement Tools	X	
Report Generation	X	
Software Mode (Validation) for Laser Beam Alignment	X	

I. Non Clinical Testing.

The LYKOS and ZILOS-tk image quality, laser focus, zona pellucida penetration and software have been verified and validated, and laser pulse duration, laser pulse power, laser mean power limits, RED-i directionality and laser focus have all been tested and shown to be equivalent to the predicates.

J Conclusions.

LYKOS and the modified ZILOS-tk are substantially equivalent to the predicate 1 ZILOS-tk:

1. They share the same software code.
2. They have the same Indications for Use and their applications are identical.
3. Their operational principles are the same.
4. The Multipulse Mode has been shown to result in similar or lower heating as the predicate single-pulse laser, to which it is therefore commensurate.
5. The use of the visible directional beam to indicate the target is functionally equivalent to Predicate 2, Saturn.

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

APR 2 4 2012

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BEVERLY MA 01915

Re: K120055
Trade/Device Name: ZILOS-tk [Zona Infrared Laser Optical System – Turn Key]
LYKOS
Regulation Number: 21 CFR§ 884.6200
Regulation Name: Assisted reproduction laser system
Regulatory Class: II
Product Code: MRX
Dated: March 27, 2012
Received: March 28, 2012

Dear Mr. Douglas-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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K120055

Device Name: ZILOS-tk [Zona Infrared Laser Optical System – Turn Key]

LYKOS

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120055