DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2004

Mr. Diarmaid Douglas-Hamilton
Senior Vice President, R&D
Hamilton Thorne Biosciences, Inc.
100 Cummings Center, Suite 465E
BEVERLY MA 01915-6143

Re: K040045
Evaluation of Automatic Class III Designation
Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®)
Regulation Number: 21 CFR 884.6200
Classification: Class II
Product Code: MRX

Dear Mr. Douglas-Hamilton,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®). 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 patients with otherwise poor prognosis for successful pregnancy outcome, such as advanced maternal age, prior failed in vitro fertilization procedures, cryopreserved embryos, or abnormal zona pellucida morphology. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) and substantially equivalent devices of this generic type into class II under the generic name, Assisted Reproduction Laser System. This order also identifies the special controls applicable to this device, entitled, "Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems."

FDA identifies this generic type of device as:

21 CFR 884.6200 Assisted Reproduction Laser System

An assisted reproduction laser system 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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA

rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device.

On August 25, 2004, FDA filed your petition requesting classification of the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on August 10, 2004 automatically classifying the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) in class III, because it was not within a type of device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) 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 patients with otherwise poor prognosis for successful pregnancy outcome, such as advanced maternal age, prior failed in vitro fertilization procedures, cryopreserved embryos, or abnormal zona pellucida morphology, can be classified in class II with the establishment of special controls. FDA believes that class II special controls, when combined with general controls, provide reasonable assurance of the safety and effectiveness of the device.

The potential risks to health associated with the device are: damage to the embryo, ineffective treatment, hazards associated with electrical equipment, and electromagnetic interference and electrostatic discharge hazards. The special controls guidance document aids in mitigating the risk by establishing performance characteristics, safety testing, and appropriate labeling.

In addition to the general controls of the act, the Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) is subject to the following special controls: Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems.

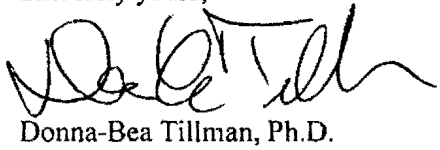
Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the assisted reproduction laser system they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Michael Bailey, Ph.D., at (301) 594-1180, extension 130.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
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