Hamilton Thorne Research
100 Cummings Center, 102 C
181 Elliott Street
Beverly, Massachusetts 01915

MAR 1 3 2002

K012805

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. **Submitter's name:** Hamilton Thorne Research
   Submitter's address: 100 Cummings Center, Suite 102-C
   Beverly, MA 01915
   Submitter's telephone No.: 978 -921-2050

   Contact Person: Diarmaid Douglas-Hamilton,
   Vice President, Research and Development

   Date Summary Prepared: August 17, 2001

2. **Trade or proprietary name:** AutoMARQER™
   Common or usual name: Differential spectrophotometer/reflectometer
   Classification name: Hematology
   Class: II

3. **Legally marketed predicate device:** IVOS Sperm analysis system
   [Hamilton Thorne Research (K920719, SE 6/29/92)]

4. **Subject device description:**
   The AutoMARQER™ functions as a differential spectrophotometer / reflectometer, using MARQ™ Plus Test Kits* for sperm analysis.

   The AutoMARQER conducts sequential measurement operations on a specimen introduced into the instrument on a special MARQ™ Plus Test Kit cassette designed for use with the AutoMARQER.

   When using the FertilMARQ Plus Test Kit,* the AutoMARQER measures sperm concentration, motility and velocity. The AutoMARQER performs as a spectrophotometer when measuring specimen concentration. When measuring motility and velocity, it measures light scatter that occurs as sperm intercept its laser beam. It measures number of sperm in a beam directly by counting sperm cells crossing the beam and determines their velocity by the length of beam passage. Since the beam diameter is known, the crossing time gives the sperm velocity

   * *Embryotech Laboratories, Wilmington, MA, commercializes the MARQ™ Plus Test.*

5. **Subject device intended use:**

The AutoMARQER™ is a differential spectrophotometer/reflectometer for sperm analysis and quantification, using MARQ™ Plus Test Kits.

6. **Performance data:**

Equivalent results are obtained on semen samples analyzed by both the AutoMARQER™ and the IVOS™ Sperm analysis system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Hamilton Thorne Research
c/o Diarmaid Douglas-Hamilton
Vice President, Research and Development
100 Cummings Center, Suite 102-C
Beverly, MA. 01915

JUN 15 2012

Re: k012805
Trade/Device Name: AutoMARQER™
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Date: January 12, 2002
Received: January 25, 2002

Dear Dr. Diarmaid Douglas-Hamilton:

This letter corrects our substantially equivalent letter of March 13, 2002.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

C. Indications for use of the Device

510(k) Number): [To be assigned]

Device Name: AutoMARQER™

Indications for Use:

The AutoMARQER™ is a differential spectrophotometer/reflectometer for sperm analysis and quantification, using MARQ™ Plus Test Kits.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012805

Prescription Use X **or Over-the-Counter Use** ___

(Per 21 CFR 801.109) (Optional Format 1-2-96)