

3/19/99

Hamilton Thorne Research, Inc.  
Premarket Notification  
AUTOMARQER™

K990184

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### 510(k) Summary

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

(A)(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  
  
Date Summary Prepared: January 8, 1999

(2) Trade or proprietary device name: Automarqer™  
Common or usual name: Differential spectrophotometer  
Classification name: Hematology

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

(4) Subject device description:

The Automarqer™ is a differential spectrophotometer for quantification of results using MARQ™ Test Kits \* for sperm analysis. The MARQ test kits employ a unique test cassette with four wells, each containing a filter to retain the test reagents and sample suspension. The test cassette is designed to be inserted into the Automarqer for reading of results after the sample has been processed. The Automarqer provides the numeric analysis of the quantity of sperm or other sperm ejaculate component being evaluated.

The Automarqer operates by measuring the well reflectivity in two wavelengths (red and green) and deriving the optical absorption in DNA-specific dyes within the wells, generated by the staining reagents used in the MARQ test kits. Each well emits a signal in the color with which it is illuminated (either red or blue dye). The first well of the test cassette provides a standard signal (using a standardized latex bead suspension), the second well provides a null signal, and the third and fourth wells provide sample signals.

The Automarqer contains an optical assembly, microprocessor and program, cassette position sensor and readout screen. Software in the microprocessor ROM directs the operations. The microprocessor detects position of the cassette as each well is inserted, stores the value of the signal from each well separately under red and green wavelength illuminations, and computes the corresponding reflectivity of the sample, using the scale defined by the difference between the first two wells (the standard signal and the null signal). In this way, the system is self-calibrating on each cassette.

\* MARQ™ Test Kits are being developed for commercialization by Embryotech Laboratories, Wilmington, MA.

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(5) Subject device intended use:

The Automarqer™ is a differential spectrophotometer for quantification of results using Ferto;MARQ™ Test Kit for sperm concentration analysis.

(6) Performance data:

Equivalent results are obtained on semen samples analyzed by both the Automarqer™ and the IVOS sperm analysis system. Only slight variability has been observed due to the instrument and test cassette design themselves, or to the bead suspension used in the test well for self-calibration. The precision and repeatability of the Automarqer in application is very good, with most of the observed error in the studies coming from the differences in the sample and its administration in the test.

Coefficients of Variation due to equipment (Automarqer, cassette) and sample

Automarqer well variability	< 0.15%
Cassette well variability	1.1%
Sample well variability	2.4%
simulated sample variability	20%
actual sample variability	16%

35 clinical samples obtained for analysis of sperm concentration by both the Automarqer and the IVOS show high degree of correlation,  $r = 0.997$ , and samples run by three different operators on 11 samples also showed reproducibility.



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

DEC 21 2012

Re: k990184

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 8, 1999  
Received: January 20, 1999

Dear Dr. Diarmaid Douglas-Hamilton:

This letter corrects our substantially equivalent letter of March 19, 1999.

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* Diagnostics and Radiological Health  
Center for Devices and Radiological Health

Enclosure

Hamilton Thorne Research, Inc.  
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**C. Indications for use of the Device**

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510(k) Number): ~~Not known~~ K990184

Device Name: Automarqer™

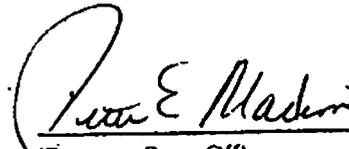
Indications for Use:

The Automarqer™ is a differential spectrophotometer for quantification of results using MARQ™ Test Kits for sperm analysis.

*(Please do not write below this line—continue on another page if needed)*

\* \* \* \* \*

**Concurrence of CDRH, Office of Device Evaluation (ODE)**



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number \_\_\_\_\_

Prescription Use X Or Over-the-Counter Use  
(Per 21 CFR 801.109) (Optional Format 1-2-96)