

K983473

DEC 17 1998

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: Embryotech Laboratories, Inc.
Submitter's address: 323 Andover Street, Wilmington, MA 01887
Submitter's telephone number: (978) 658-4600
Contact Person: Ann D. McGonigle, Regulatory Affairs (508) 358-9114

Date Summary Prepared: September 30, 1998

- (2) Trade or proprietary device name: FertilMARQ™ Test Kit
Common or usual name: Semen analysis test kit
Classification name: Obstetrics/gynecology

- (3) Legally marketed predicate device: Semen Analysis Kit [Humagen Fertility
Diagnostics] (K915229, 08/30/94)

- (4) Subject device description:

The FertilMARQ™ Test Kit is an *in vitro* test kit for the analysis of sperm concentration. Each kit provides sufficient components to perform analysis of two separate semen samples in duplicate. The kit contains components intended to hold, treat, and test collected semen (pre-coated collection cups, disposable pipettes, test cassettes), reagents intended to stain and wash semen samples collected on the test cassette. Positive and negative control wells are incorporated into the cassette design. In addition, the package insert and a Test Results form are included in the Kit. The Kit and all components are stored at room temperature.

The test operates by physical separation of sperm from seminal plasma and other semen components after a sample is dropped onto the filter incorporated into the test cassette. The staining reagent (Thiazine Blue) reacts with multiple components present in the differentiated sperm to provide an average signal that is representative of the entire sperm population. Hundreds of thousands to millions of sperm cells are captured and yield a colorimetric result indicating sperm concentration as above or below 20 million/mL (20 M/mL) sperm, as compared to the negative control result, an intrinsic part of the assay.

- (5) Subject device intended use:

The FertilMARQ™ Test Kit is a semi-quantitative test for the rapid analysis of sperm concentration to aid in the determination of male infertility.

- (6) Performance data:

Equivalent results are obtained on semen samples analyzed by both the FertilMARQ™ Test Kit and the standard manual microscopic analysis method.

Of the 162 semen samples evaluated in a three site clinical evaluation, 117 had sperm concentrations equal to or above 20 million/mL and 45 had sperm concentrations below 20 million/mL. 116 out of 117 samples above 20 million/mL were correctly identified as positive and 43 out of 45 samples below 20 million/mL were correctly identified as negative by the FertilMARQ™ Test Kit, based on comparison to light microscopic method result. These data demonstrated the FertilMARQ™ Test Kit Sensitivity = 98%; Specificity = 98%; Accuracy = 98%; Positive predictive Value = 99%; and Negative predictive value = 96%.

In a dilution study at the critical cutoff range, 18 of 19 semen samples with sperm concentrations above 20 million/mL were correctly identified, and 12 of 13 semen samples with sperm concentrations below 20 million/mL were correctly identified, based on comparison to result obtained by the manual light microscopic method. The two other samples were found to be borderline or inconclusive by the FertilMARQ Test Kit.

Reproducibility studies also demonstrated that corresponding results were obtained at two sites on the same sample in 48 out of 50 samples, even when semen samples were analyzed 24 hours apart. Each site had one discrepant negative finding where microscopic analysis found concentrations over 20 million/mL. Each laboratory testing the 50 samples had an overall accuracy of 97.5%.

Intra-laboratory testing at one of the clinical evaluation sites resulted in 101 of 102 samples tested having concordant results when the same semen sample was tested by two separate operators.



Embryotech Laboratories, Inc.
c/o Ms. Ann D. McGonigle
Regulatory Consultant
323 Andover Street
Wilmington, MA 01887

JUN 15 2012

Re: k983473

Trade/Device Name: FertilMARQ™ Test Kit
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Date: September 30, 1998
Received: October 2, 1998

Dear Ms. McGonigle:

This letter corrects our substantially equivalent letter of December 17, 1998.

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

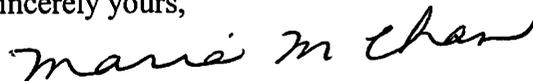
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medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your 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

Embryotech Laboratories, Inc.
Premarket Notification
FertilMARQ™ Test Kit

C. Indications for use of the Device

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510(k) Number: ~~Not known~~ K983473

Device Name: FertilMARQ™ Test Kit

Indications for Use:

The FertilMARQ™ Test Kit is a semi-quantitative test for the rapid analysis of sperm concentration to aid in the determination of male infertility.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K983473

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