EMBRYOTECH™ AUG 1 5 2001

laboratories

## 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 AND 21 CFR 807.92.

The assigned 510 (k) number is: K011679

(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 consultant to Embryotech Laboratories
(508) 358-9114

Date Summary Prepared: May 21, 2001

(2) Trade or proprietary device name: FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility

Common or usual name: Semen analysis test kit
Classification name: Obstetrics/gynecology

(3) Legally marketed predicate device: Embryotech FertilMARQ™ Test Kit [Embryotech Laboratories, Inc. (K983473, 12/17/98)]

(4) Subject device description:

The FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility 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. The kit contains components intended for collection, preparation and testing of semen samples (pre-coated collection cups, disposable droppers, test cassettes), and the reagents to stain and wash semen samples on the test cassette. A package insert that includes a FertilMARQ Sperm Concentration Test Results form is included in the Kit. The Kit and all components are stored at room temperature.

The Kit test cassette has four wells and allows the user to perform two separate tests. For each test, there is reference color control well and an adjacent test well provided. There are two sets of reference color wells and adjacent test wells on the cassette.

| | True Negative results | True Positive results |
|---|---|---|
| **Site 1**: | 14 /79 < 20 M/mL by professional user | 65 /79 > 20 M/mL by professional user |
| **Site 2**: | 9 /43 < 20 M/mL professional user | 34 /43 > 20 M/mL by professional user |
| **Site 4**: | 13/72 < 20 M/mL by professional user | 59 /72 > 20 M/mL by professional user |
| | 36/194 < 20 M/mL | 158/194 > 20 M/mL |

- Out of 158 true positives, home users correctly identified 141 as positive (Positive predictive value = 89%).
- Out of 36 true negatives, home users correctly identified 27 as negative (Negative predictive value = 75%)

Calculated Contingency results:

| | |
|---|---|
| Sensitivity = 94% | Positive predictive Value = 89% |
| Specificity = 61% | Negative predictive value = 75% |
| Accuracy = 78% | |

(2) Conclusions of Comparison studies

Results obtained on semen samples analyzed by both professional and lay user using the FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility demonstrated that the kit is substantially equivalent to the predicate device and that lay users can understand and use the kit with instructions for use given and obtain comparable results to professional findings.

(5) Subject device Intended use:

The FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility is a rapid test of your semen for sperm concentration. It will measure sperm as either above or below the cutoff of 20 million sperm cells per milliliter (mL). Two test results of less than 20 million cells/mL are an indicator of male infertility.

(6) Test Characteristics:

The test operates by liquefaction of sperm ejaculate in a Chymotrypsin-coated cup, then filtration separation of sperm from seminal plasma and other semen components in the cassette test well(s). The staining reagent (Thiazine Blue) added to sample 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 in the test well cassette filter. The semi-quantitative test yields a colorimetric result indicating sperm concentration as above or below 20 million/mL (20 M/mL) sperm. This determination is made by visual interpretation, comparing test sample well color to the reference control well.

(B) (1) Studies establishing Substantial Equivalence

(a) The design and performance of the kit are essentially the same as the predicate device. Therefore no additional kit performance studies were performed.

(b) Results from data of clinical studies at three sites were pooled. Comparison was made between results of subjects (lay users) versus those of professional user with the FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility. Each subject produced a semen sample, tested the sample using the FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility, then provided an aliquot to be tested with the kit by a professional (lab technician).. Lay users performed the test either at home or at the clinic. Both users groups had no prior experience with the kit. Pooled data of 197 semen samples showed 88% concurrence between lab technicians and lay users, with 11% discordant and 1 % unreportable.

Further analysis of the data was performed, treating professional results as truth.

True positives = Semen samples with sperm concentrations measured by professionals above 20 million/mL

True negatives = Semen samples with sperm concentrations measured by professionals less than 20 million/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 5 2001

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

Re: K011679
Trade Name: FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility
Regulation Number: No Regulation
Regulatory Class: II
Product Code: MNA
Dated: May 21, 2001
Received: May 30, 2001

Dear Ms. McGonigle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## C. Indications for use of the Device



510(k) Number:

Device Name: FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility

Indications for Use:

The FertilMARQ™ Home Diagnostic Screening Test Kit for Male Infertility is a rapid test of your semen for sperm concentration. It will measure sperm as either above or below the cutoff of 20 million sperm cells per milliliter (mL). Two test results of less than 20 million cells/mL are an indicator 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 K011679

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