5/5/99

Attachment D

510(k) Summary

The assigned 510(k) number is K991251

Submitter Information (21 CFR 807.92(a)(1))

Submitter:	Becton Dickinson 1 Becton Drive Franklin Lakes, NJ 07417-1880
Contact:	Cindy Morrow Sr. Regulatory Specialist (408) 954-2694 (408) 954-2495 (FAX) cmorrow@bdis.com
Summary date:	April 12, 1999

Device Name/Classification (21 CFR 807.92(a)(2))

Name:	FALCON® IVF One Well Dish
Classification:	Assisted reproduction labware, Class II, 884.6160, Code: 85 MQK

Substantially Equivalent/Predicate Device (21 CFR 807.92(a)(3))

This product is being submitted according to the Federal Register notice located on page 48428 of Vol.63, No. 175 on September 10, 1998 under the title Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures.

Device Description (21 CFR 807.92(a)(4))

The FALCON® IVF One Well Dish is sterile (SAL of 10^{-6}), non-pyrogenic by Limulus Amebocyte Lysate (LAL of < 20 EU/device), and nonembryotoxic as tested by the mouse embryotoxicity assay (MEA) 2-cell method. The single-use plastic dish diameter is 60-mm, the well area is 2.45 cm^2, the well volume is 2.5 mL, and the total volume is 20 mL. The dish is sold in units of 20 dishes per bag, and 500 dishes per case.

The dishes have perfectly flat, optically clear surfaces for optimum manipulation and observation of the ova and embryos. The lids are designed for aseptic manipulation and consistent venting to maintain proper humidification. The dishes are manufactured from

K991251

virgin crystalline polystyrene tested for USP Class IV, V, and VI cytotoxicity. and the surfaces are treated to provide a more wetable or hydrophilic surface for tissue culture.

Intended Use (21 CFR 807.92(a)(5))

The FALCON® IVF Round Dish is intended for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures.

David L Ball

4/12/99

David Ball
Director of Quality Assurance/ Regulatory Affairs
Becton Dickinson

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1999

Mr. David Ball
Director of Quality Assurance /Regulatory Affairs
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, NJ 07417-1884

Re: K991251
FALCON®IVF One Well Dish
Dated: April 12, 1999
Received: April 13, 1999
Regulatory Class: II
21 CFR 884. 6160/Procode: 85MQK

Dear Mr. Ball:

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) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment C

K991251

Indications for Use

510(k) Number: K991251

Device Name: FALCON® IVF One Well Dish

The FALCON® IVF One Well Dish is sterile, nonpyrogenic, embryotoxicity tested, single-use plasticware intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction techniques.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991251