K090429

SEP 18 2009

ThermoFisher SCIENTIFIC

510(k) Summary – IVF ICSI Dish

COMPANY

Name	Thermo Fisher Scientific Labware & Specialty Plastics Business Unit [Nalge Nunc International]
Address	75 Panorama Creek Drive Rochester, NY 14625-2385 USA
Registration No.	
Contact Person	Robert Prescott, Manager, Regulatory Affairs and Quality Assurance
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Date of Summary	February 11, 2009

DEVICE

Trade name	IVF ICSI Dish
Common name	IVF tissue culture dish
Classification name	Assisted Reproduction Labware
21 CFR	884.6160
Code	MQK
K Number	K090429

Trade Name	Configuration	Catalog Number
IVF ICSI Dish	1-Well dish with lid	150265

PREDICATE DEVICE

Trade name	NewLife™ Dish
Common name	IVF tissue culture dish
Manufacturer	Humagen Fertility Diagnostics, Inc 2400 Hunter's Way Charlottesville, VA 22911
Catalog No.	14-52L
510(k) No.	K990941

DEVICE DESCRIPTION – IVF ICSI Dish

The IVF ICSI Dish is an injection molded polystyrene dish with a single dish-sized well. The dish has overall outside dimensions of 1.999" (50.77 mm) diameter and 0.340" (8.64 mm) height without the lid. Addition of the lid increases overall height to 0.384" (9.75 mm).

The dish has a fluid capacity of 12.5 ml, if filled to the top of the sidewall; however, individual IVF clinics typically use a small fraction of that potential volume.

The polystyrene used for the dish and lid are virgin crystal-grade polystyrene, which has successfully passed the USP 32 <88> Class VI test for *in vivo* cytotoxicity and USP 32 <87> for *in vitro* cytotoxicity.

The dish is designed in such a way that when the lid is mounted on the dish, dishes can be stacked. The lid can be removed with one hand.

The IVF ICSI Dish is packed in strips of 3 dishes with lids and 40 strips in a box for a total of 120 units

The IVF ICSI Dish is terminally sterilized by gamma irradiation to achieve an SAL of 10^{-6}. The dish is non-pyrogenic as tested by LAL, and non-embryo toxic as tested by one-cell mouse embryo assay (MEA).

The IVF ICSI dish is disposable and intended and labeled for single use.

INTENDED USE

The dish is intended for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).

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COMPARISON TO PREDICATE DEVICE

	IVF ICSI Dish	NewLife™ Dish
Intended use	The IVF ICSI dish is intended for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).	The NewLife™ Dish is intended to be to hold zygotes/embryos during micromanipulation or other tissue culture procedures in the IVF laboratory. NewLife™ Dishes are used in the tissue culture techniques performed by embryologists when injecting a single sperm into an egg, or assisting an embryo in hatching prior to re-implantation during the procedure of fertilization by intracytoplasmic sperm injection. The dishes are disposable tissue culture labware used in procedures that have been developed to aid infertile couples achieve pregnancy. Specifically, the ICSI procedure is beneficial where male fertility is impaired.

75 Panorama Creek Drive Rochester, NY 14625 Tel: 585.586.8800 Fax: 585.586.3294 www.thermofisher.com

	IVF ICSI Dish	NewLife™ Dish
Indication for use	The IVF ICSI dish is intended for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).	The NewLife™ Dish is intended to be to hold zygotes/embryos during micromanipulation or other tissue culture procedures in the IVF laboratory. NewLife™ Dishes are used in the tissue culture techniques performed by embryologists when injecting a single sperm into an egg, or assisting an embryo in hatching prior to re-implantation during the procedure of fertilization by intracytoplasmic sperm injection. The dishes are disposable tissue culture labware used in procedures that have been developed to aid infertile couples achieve pregnancy. Specifically, the ICSI procedure is beneficial where male fertility is impaired.
Contraindication	N/A	N/A
Target Population	Female	Female
Patient/embryo contact material	Polystyrene	Polystyrene
Design features	The bottom of the dishes is flat and optically clear. The lid can be handled by one hand while other lab equipment can be handled by the other hand. The dishes can be stacked.	The bottom of the dish is flat and optically clear either with or without etched rings.
Safety features	N/A	N/A
Other relevant characteristics	Sterile (SAL 10^{-6}), via gamma radiation Tested non-pyrogenic by LAL Passed 1-cell mouse embryo test at ≥80% expanded blastocysts at 96 hours	Sterile (SAL 10^{-6}), via gamma radiation Tested non-pyrogenic by LAL Passed 2-cell mouse embryo test at ≥70% hatched/expanded blastocysts at 72 hours

The IVF ICSI Dish and the predicate device NewLife™ Dish, have similar applications which include the ICSI technique. Both devices are sterile with SAL of 10^{-6}. They are tested non-pyrogenic by Limulus Amebocyte Lysate (LAL) and non-embryotoxic as tested by the mouse embryo assay (MEA). The dishes are made of the same material polymer (Polystyrene) and they are gamma irradiated.

The differences between the IVF ICSI Dish and the NewLife™ Dish (predicate device) are that the IVF ICSI Dish is not offered in a configuration with etched circles on the bottom. And the predicate device is tested with the 2-cell mouse embryo assay. There is no consensus among IVF clinics as to a preference for the 1-cell or 2-cell test. These differences do not affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Mr. Robert Prescott
Manager Regulatory Affairs and Quality Assurance
ThermoFisher Scientific
75 Panorama Creek Drive
ROCHESTER NY 14625

Re: K090429
Trade/Device Name: IVF ICSI Dish and IVF Center Well Dish
Regulation Number: 21 CFR §884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: August 28, 2009
Received: August 31, 2009

Dear Mr. Prescott:

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 either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Date: June 19, 2009

Indications for Use

510(k) Number (if known): K090429
Device Name: IVF Center Well Dish

Indications for Use:

"The IVF Center Well Dish is intended for preparing and culturing gametes or embryos for use in human In Vitro Fertilization (IVF)".

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090429