

FEB 18 2000

510(k) Summary

*K 994361
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Company

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Elmwood, WI 54740

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Date of Summary: 22-Dec-1999

Device

Proprietary Names: ESP Four Well Tissue Culture Plate
ESP Six Well Tissue Culture Plate
ESP Micro Six Well Tissue Culture Plate
ESP Well in Well Tissue Culture Plate
ESP Square Tissue Culture Plate with Grid

Common Name: Culture Dish
Class: II
CFR Reference: 884.6160
Prococode: 85 MQK

Predicate Device

Proprietary Name: Falcon IVF Four Well Plate
Common Name: Culture Dish
Manufacturer: Becton Dickinson Labware
Model Number: 353654
510(k) Number: K991249

Device Description

The polystyrene ESP tissue culture plates consist of a square base plate with a square lid key wayed to interlock with the base plate. The key way system keeps the lid securely on the base plate. The bottom of the base plate is recessed to allow stacking of multiple plates without the plates sliding apart. The ability to stack plates reduces space requirements during storage and incubation. The 7 cm x 7 cm square shape allows for handling ease regardless of hand size. ESP plates are sterilized using gamma irradiation.

Five configurations of ESP tissue culture plates are available. All five types of plates are identical except for the different physical configurations described below.

ESP Four Well Tissue Culture Plate

Four equally spaced wells with rounded bottoms. Each well is 3 cm in diameter and has a 5 milliliter capacity. The wells are numbered clockwise, with the numbers molded into each plate.

ESP Six Well Tissue Culture Plate

Six equally spaced wells in a circular configuration. Each well is 2 cm in diameter and has a rounded bottom with a 2.5 milliliter capacity. The wells are numbered counterclockwise, with the numbers molded into each plate.

ESP Micro Six Well Tissue Culture Plate

Six equally spaced wells in a circular configuration. Each well is 2 cm in diameter and has a rounded bottom with a 1 milliliter capacity. The wells are numbered counterclockwise, with the numbers molded into each plate.

ESP Well in Well Tissue Culture Plate

A small well (2 cm diameter) within a large well (5.5 cm diameter). The two wells are separated by a vertical wall and a flat ledge.

ESP Square Tissue Culture Plate with Grid

A flat surface marked with a square grid consisting of 25 one-half inch squares. The squares are numbered 1 – 5 across the top, and A – E down the left side. The markings are molded into the bottom side of the base, leaving a smooth working surface on the top side of the base.

Intended Device Usage

The ESP tissue culture plates are single-use labware intended for use in cell culturing and diagnostic laboratory procedures.

Comparison to Predicate Device

Table 1: Comparison of ESP Culture Plate to Falcon IVF Four Well Plate

	ESP Culture Plate	Falcon IVF Four Well Plate
Intended Use	Cell culturing, diagnostic lab procedures	Preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures.
Indications	Cell culturing, diagnostic lab procedures	In vitro fertilization techniques; tissue culture

Contraindications	N/A	N/A
Patient/Embryo-Contacting Materials	Polystyrene	Polystyrene, surface treated
Design Features	Lid is key wayed to interlock with the base plate. Bottom of base plate is recessed to allow stacking of multiple plates without the plates sliding apart. Five configurations: Four Well, Six Well, Micro Six Well, Well in Well, and Square Grid.	Plate has perfectly flat, optically clear surface for optimum manipulation and observation of ova and embryos. Lid provides access to two wells while other two remain covered. Lid design allows aseptic manipulation and consistent venting to maintain proper humidification.
Safety Features	N/A	N/A
Other Relevant Characteristics	<ul style="list-style-type: none"> • Sterile (SAL 10⁻⁶) • Non-pyrogenic by LAL • Passes one-cell MEA 	<ul style="list-style-type: none"> • Sterile (SAL 10⁻⁶) • Non-pyrogenic by LAL • Passes two-cell MEA

The ESP plates and the Falcon IVF Four Well Plate have similar applications, which include cell culturing and IVF. Both devices are sterile (SAL of 10⁻⁶), non-pyrogenic by Limulus Amebocyte Lysate (LAL), and nonembryotoxic as tested by the mouse embryo assay (MEA). The ESP plates and the Falcon plate are made from the same material, polystyrene. The ESP Four Well Plate and the Falcon IVF Four Well plate are very similar in configuration, with each plate having four wells.

The primary difference between the ESP plates and the Falcon plate is the physical configuration of the plates. The ESP plates come in a variety of configurations, including four well, six well, micro six well, well in well, and square grid. All ESP lids are key wayed to interlock with the base plate. The Falcon plate has four wells and a special lid to allow access to two wells while keeping the other two wells covered. These differences affect the ease of use of each device for varying applications. These differences do not alter the safety and effectiveness of the devices.

The Falcon plate is surface treated to improve hydrophilicity of the plate surface, whereas the ESP plates are not surface treated. However, both devices are comprised of polystyrene, which has been shown to be biocompatible (see section on Biocompatibility). The surface treating of the Falcon plate is simply an enhancement to improve the ease of use of the product. The non-treated

surface of the ESP plates does not compromise the safety and effectiveness of the ESP plates as compared to the Falcon plate.

Both the Falcon plate and the ESP plates pass the mouse embryo assay (MEA), however, the two-cell MEA was used for the Falcon plate whereas the one-cell MEA was used for the ESP plates. Currently, there is no consensus in the medical community on whether the one-cell or two-cell MEA is most appropriate. Both assays test the viability of an embryo in the test device. Since both devices passed the MEA test, both devices have been shown to be non-embryotoxic. The type of MEA test used is not relevant to the safety and effectiveness of the devices.



FEB 1 8 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Mark L. Anderson
President
Genesis Industries, Inc.
601 Pro-ject Drive
Elmwood, WI 54740Re: K994361
ESP Four Well Tissue Culture Plate
ESP Six Well Tissue Culture Plate
ESP Micro Six Well Tissue Culture Plate
ESP Well in Well Tissue Culture Plate
ESP Square Tissue Culture Plate with Grid
Dated: December 22, 1999
Received: December 27, 1999
Regulatory Class: II
21 CFR §884.6160/Procode: 85 MQK

Dear Mr. Anderson:

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

510(k) Number (if known): K994361

Device Name: ESP Four Well Tissue Culture Plate
ESP Six Well Tissue Culture Plate
ESP Micro Six Well Tissue Culture Plate
ESP Well in Well Tissue Culture Plate
ESP Square Tissue Culture Plate with Grid

Indications For Use: The ESP Tissue Culture Plates are single-use labware intended for use in cell culturing and diagnostic laboratory procedures.

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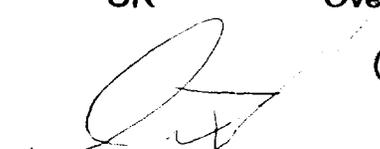
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994361