



Food and Drug Administration
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July 18, 2016

Research Instruments Limited
Wendy Hassan
Regulatory Affairs Executive
Bickland Industrial Park
Falmouth, Cornwall TR11 4TA
United Kingdom

Re: K160504
Trade/Device Name: RI Witness Embryology Heated Plate
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: MQG
Dated: June 16, 2016
Received: June 20, 2016

Dear Wendy Hassan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160504

Device Name
RI Witness Embryology Heated Plate

Indications for Use (Describe)

To maintain the temperature of human reproductive tissue such as oocytes and embryos through an assisted reproduction (AR) cycle.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K160504

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Date prepared: Monday, 18 July 2016

Device

Trade Name: RI Witness Embryology Heated Plate
Device Name: Assisted reproduction stage warmer
Device Regulation: 21 CFR 884.6120 (Assisted reproduction accessories)
Regulatory Class: II
Product Code: MQG

Predicate Device

Thermoplate Stage Warmer by Tokai Hit Co. Ltd, Shizuoka-ken, Japan, K991263

Description of the device

The RI Witness Embryology Heated Plate is designed to maintain the temperature of embryos and other reproductive tissues placed in dishes on the surface of the device. It is typically installed in a flow hood or on a work bench and comprises of a central clear window within a solid baseplate containing the temperature controller. There are 5 heating circuits, one for the window that uses ITO coated glass and the other 4 use power resistors screwed in thermal contact to the aluminium base plate.

Indications for Use

To maintain the temperature of human reproductive tissue such as oocytes and embryos through an assisted reproduction (AR) cycle.

Comparison with the Predicate Device

Intended Use

The RI Witness Embryology Heated Plate's intended use is identical to the Tokai Hit Thermoplate, as both are intended to maintain the temperature of reproductive tissue samples, for the same patient group, by the same clinician group and within similar healthcare facilities.

Technological Features

The RI Witness Embryology Heated Plate and Thermoplate operate on the same technological principle (i.e. are used to control and maintain the temperature of human reproductive tissues). Both devices provide heat via thermal conduction from a baseplate to the dish containing the tissues. The

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main appreciable differences between the two devices are that the Thermoplate has an external control unit, whereas the RI Witness Embryology Heated Plate has integral electronics. Furthermore, the Embryology Heated Plate provides a clear heated platform for the area under the microscope bonded to a plate with a large surface area so several dishes at once can be kept warm, whereas the Thermoplate consists only of a clear heated platform. The RI Witness Embryology Heated Plate is part of a radiofrequency identification (RFID) system to identify and track the lineage of the tissue samples being treated or inspected on in an assisted reproduction facility.

Technological Features	Thermoplate (K991263)	RI Witness Embryology Heated Plate (K160504)
Components	Plate with separate control unit, software	Control unit containing software, integrated into the device
Materials and processes	X2 layers of glass	ITO coated glass, Corian (mineral /acrylic composite) and aluminum base
Max heating Power	30W	20W (ITO Channel) 40W (Channel 1 to 4 each)
Heating channels	1	5
Accuracy	+/- 0.3	+/- 0.2
Heating range	0-50°C	30-45°C

Summary of Non-Clinical Performance Data

The following performance data was provided in support of the substantial equivalence determination:

Electrical Safety, Electromagnetic Compatibility (EMC), and Wireless Technology

Electrical safety and EMC testing have been conducted for the RI Witness Embryology Heated Plate. The plate complies with IEC 60601-1:2005/A1:2012 edition safety standards and IEC 60601-1-2:2014 for EMC.

The RFID component of the RI Witness Embryology Heated Plate has been tested per the FDA guidance document “Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff” issued January 3, 2007.

Software Verification and Validation Testing

Software verification and validation testing have been conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of premarket Submissions for software Contained in medical devices.” The software for this device is considered a “minor” level of concern.

Bench Testing

The RI Witness Embryology Heated Plate was subjected to testing to ensure satisfactory operating performance. These tests address the following:

- Time to reach temperature set point
- Maximum temperature
- Stability of temperature control
- Uniform distribution of temperature across the device
- Liquid ingress
- Volatile organic compound emissions
- Cable integrity up to 84°C
- Thermal Cycling Life Test
- Packaging Verification



- RFID Read Range and Read Reliability
- Mouse embryo assay to measure the effects of exposure to radiofrequency

Conclusion

The results of the testing described above provide a reasonable assurance that the RI Witness Embryology Heated Plate is as safe and effective as the predicate device and supports a determination of substantial equivalence.