JUL - 8 1999

K991263

Microscope-stage Automatic Thermocontrol System

THERMOPLATE

TOKAI HIT CO., LTD.

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510(k) Summary of THERMOPLATE Stage Warmer

(As required by 21 CFR 807.92(c))

July 5, 1999

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Trade Name of the Device: THERMOPLATE
Common Name: Stage Warmer
Classification Name: Assisted Reproduction Accessories (CFR#:884.6120)
Legally Marketed Device: 63 FR 48428 97N-0335 September 10,1998, Effective Date October 13,1998

1. Description of Device

The THERMOPLATE is a device automatically controls the temperature of specimens under the microscopes. The THERMOPLATE is made up of two sections: the plate section and the controller section. The plate section is to be set on the stage of a microscope. The specimen placed on the plate section can be maintained at an optimum temperature by the function of the heating element and the heating control unit. As a clear heating material is being coated inside the plate section, sufficient insulation is provided for the heating mechanism.

This product's electrical safety and accuracy had been proven by conforming to UL/CE standards.

2. Indication for Use

THERMOPLATE is a Stage Warmer which is used to control the temperature of specimens such as gametes and embryos observed under a microscope.

3. Technological Characteristics

1) Design features

The plate section is designed specifically to match with individual type, upright/inverted/stereo, and configuration of the microscopes.

2) Safety features

The external surface of the plate section is covered by non-electric conductible material, such as heat resisting rigid glass and resin. Accordingly hazardous events i.e. leakage of electricity and/or electric shock will not take place.

The plate is made of two pieces of rigid glass paste together with clear silicone. Accordingly, the plate has dual structure which prevents breakage of glass and by any possibility the event takes place fragment of the broken glass will not fly apart for the glasses are paste together with silicone.

3) Other features

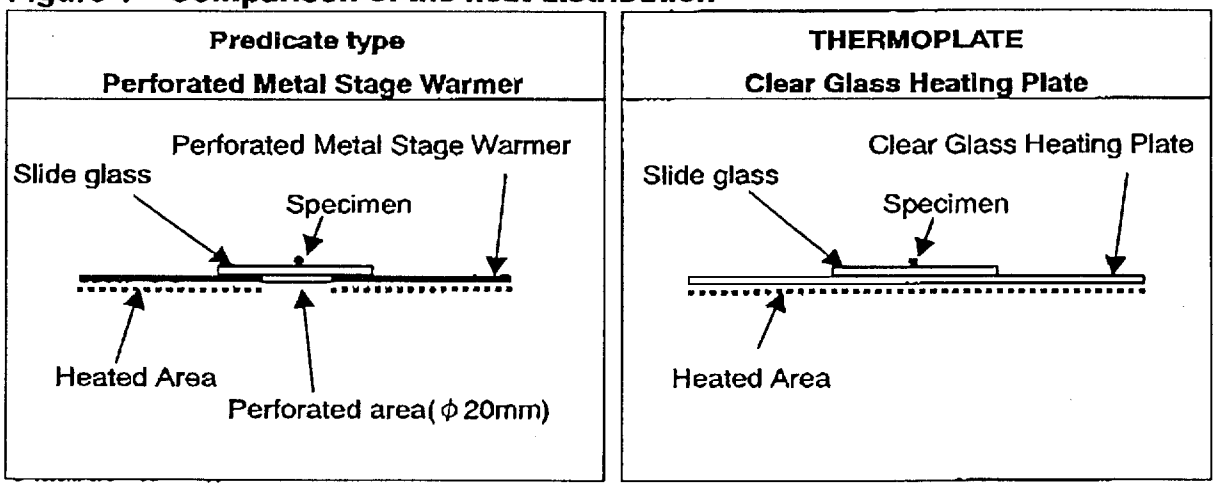
The prime characteristic of TEHRMOPLATE is that the plate section is composed of clear materials excluding the resin frame.

As a consequence of adopting clear heating plate, the device had acquired two significant features, accurate temperature control of the specimens and wide efficient area.

THERMOPATE has very strict accuracy in temperature control of the specimens for the optimum heat is supplied from right beneath the specimens regardless of the area one is placed on the plate. (Refer the drawings below) The wide efficient area allows multiple specimens to be heated at the same time and observed without replacing them as the heating plate is made of clear materials.

Along with quick start up and the most reliable accurate temperature control, THERMOPLATE provides the user easy operation and the accurate temperature control.

Figure 1 Comparison of the heat distribution



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 1999

Mr. Hideharu Tsuchiya
Director
Tokai Hit Co., Ltd.
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Shizuoka-ken
JAPAN 418-0074

Re: K991263
Thermoplate Stage Warmer
Dated: April 10, 1999
Received: April 13, 1999
Regulatory Class: II
21 CFR §884.6120/Procode: 85 MQG

Dear Mr. Tsuchiya:

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): K991263

Device Name: THERMOPLATE

Indications For Use:

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(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, ENT,
and Radiological Devices
510(k) Number K991263

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)