K121566

SECTION 5 – 510(k) SUMMARY

NOV 29 2012

Submitted By:

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Date of Submission: 22 November 2012

Name of Device.

Trade Name: BT37 Incubator
Common Name: IVF Incubator
Classification Name: Assisted Reproduction Accessory (21 CFR §884.6120)
Product Code: MQG

Predicate Device:
COOK Mini-Incubator (510(k) Number: K983642)

Device Description:
The BT37 Incubator has been designed as a bench-top incubator to provide a electronically controlled environment (temperature and humidified-gas (premixed gas; typically 6% CO_2, 5% O_2, balance N_2)) for use in cell culture as part of In Vitro Fertilization (IVF) / Assisted Reproductive Technology (ART) treatments.

The BT37 Incubator overall dimensions are 420mm wide x 270mm deep x 210mm high, with a weight of 15.5 kg.

The BT37 Incubator has two chambers each of which have been designed to hold a variety of dishes with a maximum capacity per chamber as follows:

IVF Petri Dish*	Number per Chamber
NUNC 4 well	4
NUNC 60 mm	4
NUNC 35 mm	10
MINITUB 5 well	4
FALCON 60 mm	4

*This list is an example of available IVF dishes.

In case of external power failure, the BT37 incubator is equipped with an internal backup battery to maintain functionality for up to 120 minutes.

SECTION 5 – 510(k) SUMMARY

The BT37 Incubator provides an environment with elevated humidity by bubbling the incoming gas through a heated humidification bottle containing water. This gas this then passed to the left and right incubation chambers.

In its default configuration, the BT37 normally provides gas at a constant flow rate of 30 mL/min. After closing the lids, an increased gas flow at 360 mL/min is provided for 3 minutes to purge the systems. After fitting a new bottle, a triple length purge of 360 mL/min for 9 minutes is provided.

An alternative pulsed flow regime is available, where the normally constant flow of 30 mL/min can be replaced by a flow that pulses between a high and low rate. The default for these settings are normally 60 mL/min and 20 mL/min respectively with a time ratio designed to provide a mean flow of 30 mL/min. This flow approach is not normally used.

Indication for Use:
The Planer BT37 Incubator is intended to be used to provide an environment with controlled temperature at or near body temperature, CO_2, O_2 and N_2 gases, and elevated humidity for the development of gametes and embryos during in vitro fertilization (IVF) / assisted reproductive technology (ART) treatments.

Substantial Equivalence:
The Planer BT37 Incubator is substantially equivalent with respect to the intended use of the published predicate device description and technological characteristics: a dual chamber format is used; each chamber is independently controlled (temperature); the same gasses are used; the same process of supplying the gasses is used; and an equivalent humidification process is used. In both the predicate device and the BT37 Incubator, a filter is used on the humidification bottle to filter contaminates from the gas and prevent it entering the chambers.

From the viewpoint of the dishes used with the device, the two units are equivalent. The Primary differences are in the technologies used to control the gas flow and the temperatures, and the design of the user interface.

The BT37 Incubator provides the following features that are different from those found on the predicate device. Note that these features do not alter the fundamental function of the equipment and do not impact on the safety of the device.

The unit incorporates an external communication port that enables remote monitoring of the system.

The unit incorporates an inlet routing guide to ensure that the tube routing from the humidification bottle to the chambers is controlled, repeatable and not subject to temperature changes that could cause excessive condensation in the tubes.

The unit incorporates a two line liquid crystal display (LCD) allowing different parameters to be viewed.

The gas flow through the humidification bottle is visible via the front panel which allows visual feedback that the system is operating.

SECTION 5 – 510(k) SUMMARY

The unit provides a pulsed-flow feature that is not available on the predicate device. In normal use, non-pulsed, both the predicate device and the BT37 Incubator provide a constant flow of 30 mL/min shared between the left and right-hand sides of the incubator. In the BT37 incubator's pulsed-flow mode, the BT37 incubator maintains a mean flow by alternating between a low flow rate and a high flow rate. The default flow pattern is 20 mL/min for 900 s followed by 60 mL/min for 300 s which results in a mean flow of 30 mL/min; identical to that provided using the normal non-pulsed operating mode.

A summary of the device comparison is shown in the table below.

Function	Planer BT37 Incubator	Cook Mini-Incubator	Equivalence
Construction	Benchtop unit. Aluminium chambers, with hinged lid. Simple cam mechanism to clamp lid shut and sealed with an O-ring seal.	Construction is similar.	Yes
Indication for use	The Planer BT37 Incubator is intended to be used to provide an environment with controlled temperature at or near body temperature, CO_2, O_2 and N_2 gases, and elevated humidity for the development of gametes and embryos during in vitro fertilization (IVF) / assisted reproductive technology (ART) treatments.	Intended to be used to store and preserve gametes and/or embryos at or near body temperature.	Yes. The Planer BT37 Incubator statement explicitly states the gases used and the fact that the humidity is elevated. This does not represent a change in use but merely reflects the fact that statements for devices raised after clearance of the predicate device have tended to provide more detail.
Gas supply	Blend of 6% CO2, 5% O2, 89% N2	Similar	Yes
Gas supply pressure	150 kPa +/- 15 kPa	Same	Yes
Gas flow rate capability per side	0 mL/min to 450 mL/min. Normal bleed set to 15 mL/min and purge at 180 mL/min for 3 minutes. Flows fully adjustable in 1 mL/minute increments.	15 mL/min to25 mL/min in 5 mL/min increments. Purge at 175 mL/min per chamber for 3 minutes.	Yes. The Planer BT37 provides finer flow adjustment across a wider range of values.
Gas flow rate accuracy (normal flow)	±10% of flow per chamber	±15% of flow per chamber (normal flow) ±18 ml/min per chamber (purge)	Yes. Flow accuracy of the BT37 is slightly better during normal flow.
Gas flow pattern	Pulsed or non-pulsed (constant) flow pattern.	Non-pulsed (constant)	Yes, although the BT37 also supports a pulsed-flow operating mode.
Chamber temperature capability	(ambient + 5 °C) to (ambient + 20 °C) Upper temperature must not exceed 40 °C.	35.0 °C to 40.0°C in 0.1°C increments in an ambient temperature range of +20 °C to +28 °C. At set point of 37 °C, the ambient temperature range is extended to +18 °C to +32 °C	Yes. Although phrased differently, the control ranges are equivalent.
Chamber temperature accuracy	±0.2 °C at calibration point	±0.2 °C at calibration point	Yes

Humidification system	Preheated bottle through which the incoming gas is bubbled prior to passing to the left and right chambers.	Similar	Yes

The Planer BT37 Incubator meets the requirements for 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The Planer BT37 Incubator was subjected to testing to ensure satisfactory operating performance. These tests addressed: stability and recovery for temperature, humidity and carbon dioxide; accuracy of temperature and flow; operation of alarms; and cleaning and disinfection. The Planer BT37 Incubator passed the requirements of all tests.

Accelerating ageing tests were undertaken to justify the shelf-life of the humidification bottle which is supplied sterile. These tests supported a shelf-life of 29 months at room temperature.

All functions of the software were tested and found to operate correctly with no significant anomalies remaining.

Electrical safety was confirmed by successful testing to EN61010-1:2001 and BS EN 61010-2-010. Electromagnetic compatibility (EMC) was confirmed by successful testing to EN 61236-1:2006.

Conclusion drawn from the non-clinical performance data:
From the results of the non-clinical performance data for the Planer BT37 Incubator, the conclusion can be drawn that the Planer BT37 Incubator is equivalent to the predicate device with respect to the intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 29, 2012

Planer plc
% Eric S. Gruff, Ph.D., MBA
Consultant
E4 Consulting
15696 Oakstand Road
POWAY CA 92064

Re: K121566
Trade/Device Name: BT37 Incubator
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: MQG
Dated: November 13, 2012
Received: November 14, 2012

Dear Dr. Gruff:

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 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,

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

Section 4 - Indications for Use Statement

510(k) Number (if known): K121566

Device Name: BT37 Incubator

Indications for Use:

The Planer BT37 Incubator is intended to be used to provide an environment with controlled temperature at or near body temperature, CO_2, O_2 and N_2 gases, and elevated humidity for the development of gametes and embryos during in vitro fertilization (IVF) / assisted reproductive technology (ART) treatments.

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

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
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