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K032086/51

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Summary of Safety Information *Premarket Notification, Section 510(k)*	PLANER, PLC. JUNE 9, 2003

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. *Device Name:*

Trade Name: ***Kryo ART Controlled Rate Freezer***

Common Name(s): Cryo Freezer

Classification Name(s): Assisted reproduction accessories.

2. *Establishment Name & Registration Number:*

Name: **PLANER, plc.**

Owner/Op. ID Number: 9054044

Address: Windmill Road
Sunbury
Middlesex TW16 7HD
United Kingdom
44 (0) 1932 755000 –
44 (0) 1932 755001
www.planer.co.uk

3. *Classification(s):*

§ 884.6120 Assisted reproduction accessories.
(a) Identification. Assisted reproduction accessories are a group of devices used during assisted reproduction procedures, in conjunction with assisted reproduction needles and/or assisted reproduction catheters, to aspirate, incubate, infuse, and/or maintain temperature. This generic type of device may include:

(1) Powered aspiration pumps used to provide low flow, intermittent vacuum for the aspiration of eggs (ova). (2) Syringe pumps (powered or manual) used to activate a syringe to infuse or aspirate small volumes of fluid during assisted reproduction procedures. (3) Collection tube warmers, used to maintain the temperature of egg (oocyte) collection tubes at or near body temperature. A dish/plate/microscope stage warmer is a device used to maintain the temperature of the egg (oocyte) during manipulation. (4) Embryo incubators, used to store and preserve gametes and/or embryos at or near body temperature. (5) Cryopreservation instrumentation and devices, used to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature. (b) Classification. Class II (special controls) (design specifications, labeling requirements, and clinical testing).

Classification Panel: Obstretics/Gynecology

Product Code(s): MQG

4. *Equivalent Predicate Device:*

PLANER, plc. believes that the ***Kryo ART Controlled Rate Freezer*** is substantially equivalent to the following device system marketed by Thermo Forma, Inc. of Marietta, Ohio.

K021042, CryoMed IVF Controlled Rate Freezer.

K032080
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The Thermo Forma, Inc. device is cleared for marketing, having met the requirements for a finding of substantial equivalence on May 15th, 2002. The comparison device represents a freezer system and accessories that performs substantially the same function as the present ***Kryo ART Controlled Rate Freezer***. Equivalence can be seen in the basic design, materials, intended use and performance characteristics.

5. ***Device Description:***

The ***Kryo ART*** range of controlled rate freezers have been specifically designed and configured for use in the area of assisted reproduction. The freezers are available in three chamber sizes depending on the number of samples to be frozen; 1.7 liters, 3.3 liters and 16 liters.

All models incorporate the critical features expected from a high specification biological chamber and the-180°C to +40°C temperature range allows flexibility for a wide range of applications and protocols.

All of the chamber sizes are controlled by the MRV controller system, which has been created to offer multiple protocols while remaining simple to program and operate.

All systems include power failure protection, which allows the controller to continue monitoring during mains power failures.

All software is designed, developed and maintained in accordance with the Company's internal procedures. These procedures form part of the full Quality System, which is approved to ISO 9001:1994, ISO 13485:1996 and EN 46001:1996

Performance testing is complete. Units were tested according to a specific protocol. Testing demonstrates the functional suitability of the ***Kryo ART Controlled Rate Freezer*** for their intended purpose.

The ***Kryo ART*** brand of controlled rate freezers are intended to be used to freeze gametes or embryos at a user determined rate.

6. ***Applicant Name & Address:***

Windmill Road
Sunbury
Middlesex TW16 7HD
United Kingdom
44 (0) 1932 755000
44 (0) 1932 755001
www.planer.co.uk

7. ***Company Contact:***

Regulatory Affairs
Windmill Road
Sunbury
Middlesex TW16 7HD
United Kingdom
44 (0) 1932 755000
44 (0) 1932 755001
www.planer.co.uk

8. ***Submission Correspondent:***

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2004

PLANER, plc.
% Mr. David Schlerf
Official Correspondent
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
PLEASANT HILL CA 94523-3389

Re: K032086
Trade/Device Name: Kryo ART Controlled Rate Freezer
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: 85 MQG
Dated: November 10, 2003
Received: December 22, 2003

Dear Mr. Schlerf:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use:

510(k) Number: K032086

Device Name: Kryo ART Controlled Rate Freezer

Indications For Use:

The ***Kryo ART*** brand of controlled rate freezers are intended to be used to freeze gametes or embryos at a user determined rate.

Prescription Use ___X___ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K032086