OriGen
BIOMEDICAL

AUG 0 6 2002

K02 1702

510(k) Summary
OriGen Tissue Storage bags

May 19, 2002

Common Name: Tissue Storage Bags, classification LPZ
Classification Name: Tissue Freezing bag, per 21 CFR 880

OriGen Tissue storage bags are indicated for use in protecting, storing and freezing cells and tissues. These are the same devices originally approved under K915471. This 510(k) application is being submitted to document the change of sterilization method from Ethylene Oxide to radiation. Physical testing has demonstrated that there is no change in product characteristics or performance following radiation sterilization, and there is the obvious benefit of eliminating EtO residues from the device.

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Sincerely,

Richard L. Martin
President

2525 Hartford Road, Austin, TX, USA 78703 Tel: +1 512 474 7278 Fax: +1 512 708 8522

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Mr. Richard Martin
President
OriGen Biomedical, Incorporated
9709-A Beck Circle
Austin, Texas 78758

Re: K021702
Trade/Device Name: Cryobag, Model CB
Regulation Number: None
Regulation Name: Tissue Storage Bag
Regulatory Class: Unclassified
Product Code: LPZ
Dated: May 21, 2002
Received: May 23, 2002

Dear Mr. Martin:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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). 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER : K021702

DEVICE NAME : OriGen Tissue Storage Bags

INDICATIONS FOR USE :

The OriGen tissue storage bags are indicated for use in protecting, storing and freezing cells and tissues.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021702