510 (k) SUMMARY- CryoSeal® FS Applicator System K071126

Submitter Name: ThermoGenesis Corp.
Submitter Address: 2711 Citrus Road
Rancho Cordova, CA 95742

AUG 16 2007

Contact Person: John Chapman PhD
VP, Scientific Affairs
Phone Number: 916.858.5132
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Date Prepared: April 19, 2007

Device Trade Name: CryoSeal® FS Applicator System

Classification Number: 21 CFR 880.5860
Classification Name: Syringe, Piston
Product Code: FMF

Predicate Devices: Baxter Healthcare Corp., DuploReach, K014088
Baxter Healthcare Corp., Duploject Easy-Prep System, K020666

Statement of Intended Use: The CryoSeal® FS Applicator System is intended for the simultaneous application of the two components of CryoSeal FS (fibrin sealant) onto the incised liver surface in patients undergoing liver resection.

Device Description: The CryoSeal® FS Applicator System is composed of a thermoplastic polystyrene applicator handle, and two types of dispensing tips with a Y-body manifolds for application of the fibrin sealant: line/drop tips (5 and 10 cm lengths) and spray tips (3 configurations).

Comparison to the Predicate Devices: This device, with respect to material composition, device characteristics, principles of operation, and intended use, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

John Chapman, Ph.D.
Vice President, Scientific Affairs
ThermoGenesis Corporation
2711 Citrus Road
Rancho Cordova, California 95742

AUG 16 2007

Re: K071126
Trade/Device Name: CryoSeal® FS Applicator System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 27, 2007
Received: July 30, 2007

Dear Dr. Chapman:

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.

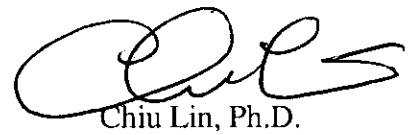
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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 (if known): K071126

Device Name: CryoSeal® FS Applicator System

Indications for Use:

The CryoSeal® FS Applicator System is intended for the simultaneous application of the two components of CryoSeal FS (fibrin sealant) onto the incised liver surface in patients undergoing liver resection.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

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

510(k) Number: K071126