K060054

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510(k) Summary

Device Name

Oncobionic System

NOV 21 2006

Common or Usual Name

Tissue Ablation System

510(k) Owner's Name, Address, Phone and Fax Numbers, and Contact Person

Oncobionics, Inc.
30211 Avenida de las Banderas, Suite 200
Rancho Santa Margarita, CA 92688
Phone Number: (949) 888-6658
Fax Number: (949) 888-6659

Contact Person: Paul Mikus, Regulatory Manager

Predicate Device:

The Guidant Microwave Ablation System (K041340) and Medtronic Cardioblate Bipolar Radiofrequency Ablation (K031247).

Date Prepared:

October 30, 2006

Indications For Use:

The Oncobionic System is indicated for surgical ablation of soft tissue, including cardiac and smooth muscle.

Device Description/Technological Characteristics:

The Oncobionic System comprises a low energy direct current (LEDC) Generator and two Electrodes. The Oncobionic System applies a LEDC pulse or series of pulses between two electrodes to ablate tissue.

Performance Data:

The submission included data from *in-vitro* testing to confirm the proof of concept and *in-vivo animal tissue* testing regarding the use of different voltages of electric current to determine the minimum voltage needed to achieve the target lesion size. In addition, Oncobionics conducted in vivo testing comparing the Oncobionic System to the Guidance Microwave System in ablating pig liver and cardiac tissue using the treatment parameters recommended in the labeling for each device. These studies show that the Oncobionic System is at least as safe and effective as the predicate devices.

Substantial Equivalence

The Oncobionic System has the same indication for use of ablating soft tissue as the Medtronic's Cardioblate and the Guidant Microwave Ablation System and the same indications for use of ablating cardiac tissue and smooth muscle as the Guidant Microwave Ablation System. The Oncobionic System, like Medtronic's Cardioblate and the Guidant Microwave Ablation System, is made of stainless steel. All of these devices use one or more electrodes or probes with a needle tip to deliver the energy to the target tissue. The Oncobionic System has some technological differences compared to the predicate devices; namely, that it delivers low energy direct current to ablate tissue, while the Medtronic's Cardioblate delivers radiofrequency electric energy and the Guidant Device delivers microwave energy to ablate. However, the Oncobionic System and the Medtronic Device are bipolar devices, although the Medtronic's Cardioblate is also a monopolar device. Moreover, performance data demonstrates that the Oncobionic System is as safe and effective as the Guidant Device in ablating soft tissue and cardiac tissue. Thus, the Oncobionic System is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2009

Oncobionic Incorporated
c/o Ms. Laurie A. Clark
King & Spalding
1700 Pennsylvania Avenue
Washington, DC 20006

Re: K060054
Trade/Device Name: Oncobionic System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II (two)
Product Code: OCL, OAB
Dated: November 1, 2006
Received: November 1, 2006

Dear Ms. Clark:

This letter corrects our substantially equivalent letter of November 21, 2006.

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 (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 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 continue 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) 276-0120. 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060054

Indications for Use

510(k) Number:

Device Name: Oncobionic System

Indications for Use: The Oncobionic System is indicated for surgical ablation of soft tissue, including cardiac and smooth muscle.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060054