K080376

Attachment 2

510k Summary

APR - 2 200

This 510(k) Summary is submitted in accordance with 21 CFR §807.92 as amended in the Final Rule published in the Federal Register Vol. 59, No. 239, 12-14-94, p. 64295.

Company Information

Name	Oncobionic Incorporated
Address	30211 Avenida de las Banderas Suite 200
	Rancho Santa Margarita, CA 92688
Telephone Number	949.888.6658
Contact Person	Paul Mikus
Date Submitted:	February 8, 2008

Device Information:

Name of Device	Oncobionic System
Common Name:	Tissue Ablation Device
Classification:	Electrosurgical Cutting and Coagulation Device

Predicate Device Information:

Oncobionic System K060054

Rita Medical UniBlate Device (K070101)

510k Summary

Device Description:

The Oncobionic System includes additional treatment parameters. These additional treatment parameters allow for the application of the Oncobionic System to target and ablate additional volumes of soft tissue. The Oncobionic System with additional treatment parameters applies a LEDC pulse or series of pulses between two electrodes to cause an ablation effect to occur. The fundamental application and design of the device has not changed, but new treatment parameters have been tested and added to the device to cause additional volumes of soft tissue ablation

Intended Use:

The Oncobionic System is indicated for surgical ablation of soft tissue

Comparison to Predicate Device:

The Oncobionic System creates equivalent tissue ablation to the Rita Medical UniBlate Device (K070101). The Oncobionic System is as safe and effective as the Oncobionic System K060054. We have compared the efficacy of our device to the predicate devices and found them to be equivalent.

Performance Data:

We have included in-vivo test data, Attachment 1, which shows the Oncobionic System to be at least as safe and effective as the predicate devices. This test shows that the Oncobionic System is substantially equivalent to the predicate devices for creating ablation zones in soft tissue.

Sterilization Validation:

The Sterilization method used for the single use Oncobionic System electrode is Ethylene Oxide Sterilization.

Software Validation:

The Company certifies that it used an adequate test plan to validate the Oncobionic System controlling software. The testing demonstrated that the functional requirements were met, and system specifications were fulfilled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2008

Oncobionic Incorporated
% Mr. Paul Mikus
Regulatory Manager
30211 Avenida de las Banderas
Suite 200
Rancho Santa Margarita, California 92688

Re: K080376
Trade/Device Name: Oncobionic System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: OAB
Dated: February 8, 2008
Received: February 12, 2008

Dear Mr. Mikus:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use

510(k) Number: K080376

Device Name: Oncobionic System

Indications for Use: The Oncobionic System is indicated for surgical ablation of soft tissue

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)

Nick R Ogle for mxn

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

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