OCT 2 4 2011

SECTION 5
510(k) SUMMARY (CONT.)

510(k) Notification K 102329

GENERAL INFORMATION

Applicant:

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Oncology
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Fremont, CA 94538
U.S.A.
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Contact Person:

Michael Sharp
Vice President, Regulatory and Medical Affairs
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Date Prepared: August 16, 2010

DEVICE INFORMATION

The NanoKnife System transmits low energy direct current (LEDC) energy from the Generator to Electrode Probes placed in a target area for the surgical ablation of soft tissue.

Classification:

21CFR§878.4400, Electrosurgical Cutting and Coagulation Device and Accessories

Product Code:

OAB

Trade Name:

NanoKnife® System

Generic/Common Name:

Low energy direct current non-thermal ablation device

SECTION 5
510(k) SUMMARY (CONT.)

PREDICATE DEVICE

The NanoKnife System is substantially equivalent to its predecessors, the Oncobionic System with 6 Probe Output (K080202) and the Oncobionic System (K080376). The NanoKnife System is a modified version of these predicate devices that has the same device configuration as the Oncobionic System with 6 Probe Output (K080202). The NanoKnife System includes single-use, disposable Electrode Probes that are substantially equivalent to those utilized by the predicate devices.

INTENDED USE

The NanoKnife System with six outputs is indicated for the surgical ablation of soft tissue.

PRODUCT DESCRIPTION

The NanoKnife System includes multiple components. The first component of the system is the Generator. The Generator operates outside of the sterile field and consists of an LCD Display, Console, Power Unit and Power Cord situated on a wheeled trolley and a Double Footswitch/Foot Pedal. The last component of the NanoKnife System is the sterile, single-use, disposable Electrode Probe. The NanoKnife System has the same device configuration as the Oncobionic System with 6 Probe Output (K080202) with minor design modifications to the hardware componentry and software. The range of parameters, pulse amplitude and pulse length, have been narrowed, a third option to the unsynchronized pulse per minute has been added, and touch screen capability in the GUI have been provided to the end user. The fundamental operating principle and design of the NanoKnife System is identical to the Oncobionics predicate devices.

SUBSTANTIAL EQUIVALENCE

The indications for use for the NanoKnife System are identical to the indications for use for the predicate devices. The design modifications included in this 510(k) premarket notification do not affect the currently cleared intended use or indications for use or alter the fundamental scientific technology of the predicate devices. Therefore, the NanoKnife System is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the NanoKnife System to support a determination of substantial equivalence to the predicate device. The bench testing verifies that the NanoKnife System meets all the specified performance specifications and thus, is substantially equivalent to the predicate devices.

SUMMARY

The NanoKnife System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 24 2011

AngioDynamics, Inc.
% Experien Group, LLC
Kit Cariquitan
155-A Moffett Park Drive, Suite 210
Sunnyvale, California 94089

Re: K102329
Trade/Device Name: NanoKnife® System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OAB, GEI
Dated: October 19, 2011
Received: October 24, 2011

Dear Kit Cariquitan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102329

Device Name: NanoKnife® System

Indications For Use:
The NanoKnife System with six outputs is indicated for the surgical ablation of soft tissue.

Prescription Use __X__ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102329