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510(k) Summary

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Date: February 15, 2008

Sponsor of the 510(k)

AngioDynamics, Inc.
603 Queensbury Ave
Queensbury, NY 12801
Establishment Registration number 1319211
Contact: Brian Kunst, Vice President, Regulatory Affairs and Quality Assurance
518-798-1215, x1123

Device Identification:

Proprietary Name:	Uniblate Electrosurgical Device
Common Name:	Radiofrequency probe
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Number:	21 CFR §878.4400
Classification Panel:	General and Plastic Surgery
Product Code:	GEI
Regulatory Class:	II

Legally marketed device to which equivalence is claimed:

Angiodynamics Uniblate Electrosurgical Device, 510(k) K070101
Angiodynamics (formerly RITA Medical Systems) Starburst Electrosurgical Device 510(k) K030967
Valleylab Cool-Tip Electrosurgical probe, 510(k) K052796

Intended Use / Indications

The AngioDynamics Uniblate System is intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures, such as partial or complete ablation of non-resectable liver lesions, osteoid osteoma, and palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

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Device Description

The UniBlate Electrosurgical Device is a monopolar radiofrequency (RF) device that consists of a variably insulated electrode that provides an adjustable ablation zone of 1 cm–3 cm.. The device has an attached electrical cable and infusion tubing set which connects the it directly to the RITA Medical 1500X RF generator and the IntelliFlow peristaltic pump. The electrical cable provides RF energy and temperature feedback to the generator and the pump infuses normal saline through the infusion tubing set. The UniBlate Electrosurgical Device is a single use device.

Technological Differences:

The AngioDynamics UniBlate, AngioDynamics Starburst Electrosurgical device (K030967), and Valleylab Cool-Tip (K052796) are monopolar electrodes used to deliver RF energy during open, laparoscopic or percutaneous procedures to ablate and coagulate soft tissue. The UniBlate is designed to provide a scaleable coagulation zone. The UniBlate electrode has a single active electrode that can be exposed from 1 cm to 2.5 cm by retracting an insulating sheath. The Cool-Tip has a fixed length active electrode, but is available in different sizes of 1cm, 2cm, and 3cm. The UniBlate allows for local fluid delivery as well as temperature monitoring. The Starburst SDE is a mulit-tined probe that provides an adjustable ablation zone up to 2cm.

Intended Use

The AngioDynamics Uniblate Electrosurgical Device is intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures, such as partial or complete ablation of non-resectable liver lesions, osteoid osteoma, and palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy

The Angiodynamics Starburst electrosurgical device is indicated for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures, such as partial or complete ablation of non-resectable liver lesions and palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy

The Valleylab Cool-tip RF System (generator and accessories) is intended for the use in percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions and osteoid osteoma tumors within bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AngioDynamis, Inc.
% Mr. Brian Kunst
603 Queensbury Avenue
Queensbury, New York 12804

JUL - 3 2008

Re: K080451
Trade/Device Name: Uniblate Electrosurgical Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 24, 2008
Received: May 29, 2008

Dear Mr. Kunst:

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

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

Enclosure

Indications for Use

510(k) Number (if known): K080451

Device Name: Uniblate Electrosurgical Device

Indications for Use:

The AngioDynamics Uniblate Electrosurgical Device is intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures such as partial or complete ablation of non-resectable liver lesions, osteoid osteoma, and palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080451