Appendix A: 510k Summary of Safety and Effectiveness

CONTACT INFORMATION

JUL 18 2006

Trena Depel
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COMPANY INFORMATION

Sanarus Medical, Inc.
4696 Willow Road
Pleasanton, CA 94588
Telephone: (925) 460-6080
FAX: (925) 460-0688

DEVICE NAME

Sanarus Visica® Treatment System

DEVICE DESCRIPTION

The Visica Treatment System consists of a control unit that controls one single-use, disposable (Visica Treatment Device or "cryoprobe"). The system utilizes inert argon gas as a cooling agent and helium for thawing. The control unit operates from standard 120/240 VAC wall power and is control by a CPLD (Complex Programmable Logic Device). An LED screen displays the status of the system. System control is accomplished directly through keys on the console itself.

The cryoprobe operates on the Joule-Thompson principle and the refrigerative capacity is limited only the distal tip of the probe. The cryoprobe incorporates a thermocouple to measure temperature near the probe tip. The thermocouple is mounted inside the cryoprobe tip and its signal is used to monitor and control some operations of the system. The control unit can also accommodate two independent temperature probes to monitor temperatures in the surrounding tissues. The temperature probes use standard T-type needle thermocouples.

INDICATIONS FOR USE

Indications for Use: The device is indicated for use in general surgery, gynecology and oncology. The system is designed to destroy tissue by the application of extreme cold temperatures. In addition the system is intended for use in the following indications:

K061510

General Surgery

- Ablation of breast fibroadenoma
- Localization of breast lesions

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Sanarus Visica Treatment System

SUBSTANTIAL EQUIVALENCE

The Sanarus Visica Treatment System is substantially equivalent to the Sanarus Visica Treatment System that was determined to be substantially equivalent on Oct 15 2002 (reference K022314) and on Nov 15 2005 (reference K052861).

The Sanarus Visica Treatment System has the same indications for use and technological characteristics as the predicate device. The patient contact components and component materials in both the new and predicate device are the same. The packaging materials, packaging configurations, sterilization methods and sterility assurance level are also equivalent.

Based on the indications for use, technological characteristics and performance testing results, the Sanarus Visica Treatment System does not raise significant new questions of safety and effectiveness.

PERFORMANCE TESTING SUMMARY

Performance testing confirms that modifications to the Instructions for Use meet applicable specifications and performance standards and are equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Sanarus Medical, Inc.
% Ms. Trena Depel
Director, Regulatory and Clinical
Affairs
4696 Willow Road
Pleasanton, California 94588

Re: K061510
Trade/Device Name: Sanarus Visica® Treatment System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: July 5, 2006
Received: July 6, 2006

Dear Ms. Depel:

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,

Barbara Bucchino

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: K061510

Device Name: Sanarus Visica® Treatment System

Indications for Use:

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Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Murray for MKM

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

510(k) Number K061510