

NOV 15 2005

**Appendix A: 510k Summary of Safety and Effectiveness****CONTACT INFORMATION**

Trena Depel  
Director, Regulatory and Clinical Affairs  
Telephone: (925) 460-5731  
FAX: (925) 460-0688  
e-mail: tdepel@sanarus.com

**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:

General Surgery

K052861

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- 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).

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 cryoprobe, resulting in the addition of an additional cryoprobe configuration to Sanarus Visica Treatment System, meet applicable specifications and performance standards and are equivalent to the predicate device.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K052861  
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: November 1, 2005  
Received: November 2, 2005

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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large, stylized "M" at the end.

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

Enclosure

K05-2861

## Indications for Use

510(k) Number: **K052861**

Device Name: Sanarus Visica™ Treatment System

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:

### General Surgery

- Ablation of breast fibroadenoma
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### Gynecology

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

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

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

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**510(k) Number**   K05 2861