K032506 1/2

OCT - 9 2003

# Section 2 - Summary of Safety and Effectiveness

## (1) Contact Information

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## (2) Company Information

Sanarus Medical, Inc.
5880 W. Las Positas Blvd., Suite 52
Pleasanton, CA 94588
Telephone: (925) 460-6080
FAX: (925) 460-6084

## (3) Device Name

Sanarus Centrica™ II Rotational Core Biopsy System

## (4) Device Description

The Sanarus Centrica II Rotational Core Biopsy System consists of a sticking needle, cutting cannula, fully integrated control unit and specimen container. The sticking needle is operated by the control unit and uses cold temperatures at its tip to engage the tissue to be sampled. The cutting cannula is coaxially mounted around the sticking needle and is used to core the tissue specimen. The cutting cannula will be available in several gauge sizes and lengths.

## (5) Indications for Use

The device is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

The device is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged

abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

## (6) Name of Predicate or Legally Marketed Device

Sanarus Centrica™ Rotational Core Biopsy System

## (7) Substantial Equivalence

The Sanarus Centrica II Rotational Core Biopsy System is substantially equivalent to the Centrica Rotational Core Biopsy System that was determined to be substantially equivalent on Sep 23, 2002 (reference K022879).

The Sanarus Centrica II Rotational Core Biopsy System has the same indications for use and technological characteristics as the predicate device. The patient contact components and component materials for obtaining core biopsy samples 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 Centrica II Rotational Core Biopsy System does not raise significant new questions of safety and effectiveness.

## (8) Performance Testing Summary

Performance testing confirms that the quality of samples obtained with the Sanarus Centrica II Rotational Core Biopsy System is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Ms. Trena Depel
Clinical & Regulatory Affairs Manager
Sanarus Medical, Inc.
5880 W. Las Positas Boulevard, Suite 52
Pleasanton, California 94588

Re: K032506
Trade/Device Name: Sanarus Centrica™ II Rotational Core Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: August 13, 2003
Received: August 14, 2003

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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: K032506

Device Name: Sanarus Centrica™ II Rotational Core Biopsy System

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Concurrence of CDRH, Office of Device Evaluation (ODE):

Miriam C. Provost

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

**510(k) Number** K032506

Prescription Use: X
(Per 21 CFR 801.109)