SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 2 4 2003

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Submitter: Vascular Control Systems, Inc.
32236-E Paseo Adelanto
San Juan Capistrano, CA 92675
(949) 488-8700

b. Contact Person: Al Memmolo
Vice President, Regulatory Affairs/Quality Assurance
(949) 488-8700 ext. 108

c. Date Summary Prepared: December 12, 2002

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Burbank Tenaculum

b. Classification name: Uterine Tenaculum (21 CFR §884.4530)

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

A. Company: Ron-Tech Medical Ltd.
Device: Transvaginal Ultrasound Probe Holder Device
510(k): K992071
Date Cleared: August 27, 1999

B. Company: Gilbert Surgical Instruments
Device: Sims Uterine Sound
510(k): N/A (The Uterine Sound is a Class I device which is 510(k) Exempt)

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Burbank Tenaculum is a stainless steel, ring-handled instrument with a hook at the distal end of one arm and a guide rod attached to the distal end of the other arm. The proximal end of the guide rod is threaded to guide insertion of the Vascular Control Systems Transvaginal Doppler Probe (TDP) into the vagina and secure the TDP in place.

A uterine sound is brazed at the distal end of the guide rod intended to be inserted through the cervical opening into the uterine cavity.

5. Statement of intended use:

The Burbank Tenaculum is an accessory used in conjunction with the Vascular Control Systems Transvaginal Doppler Probe. The device is intended to seize and hold the cervix and secure the Transvaginal Doppler Probe in place, while performing audible Doppler procedures.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Like the predicate Transvaginal Ultrasound Probe Holder Device, the Burbank Tenaculum is a ring-handled device with ratchet closure for seizing and holding the cervix. Also like the Transvaginal Ultrasound Probe Holder Device, the Burbank Tenaculum is designed with a hook for seizing and holding the cervix and is equipped with a mechanism to hold an ultrasound device. The Burbank Tenaculum also has a uterine sound which is substantially equivalent in design and materials as the Sims Uterine Sound. The materials used in the Burbank Tenaculum are similar to those of the predicate devices and are provided non-sterile, and reusable.

7. Brief summary of nonclinical tests and results:

The Burbank Tenaculum has been designed and tested per design control procedures and was found to meet its product specifications. The Burbank Tenaculum does not raise new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 2 4 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Control Systems, Inc.
% Mr. Heinz Joerg Steneberg
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K030078
Trade/Device Name: Burbank Tenaculum and Transvaginal Ultrasound Probe Holder
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 85 HDC
Product Code: 90 ITX
Dated: January 6, 2003
Received: January 9, 2003

Dear Mr. Steneberg:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030078

Device Name: Burbank Tenaculum

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030078