K023023
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J.1 Summary of Safety and Effectiveness

Submitter:	Nama Doddi, PhD Senior VP of R & D Vasca, Inc. 3 Highwood Drive Tewksbury, MA 01876 (978) 863-4400 (Phone) (978) 863-4401 (FAX)
Date:	September 10, 2002
Device:	LifeSite® Hemodialysis Access System
Classification:	Blood Access Device and Accessories – Class III - 21 CFR 876.5540
Predicate Device:	LifeSite Hemodialysis Access System and Medical Components Inc. Tesio®-Cath Catheter
Indications for Use:	The LifeSite Hemodialysis Access System provides fully implantable blood access for chronic (long term) hemodialysis. It is intended for use in patients who would otherwise be treated with standard cuffed hemodialysis catheters. A 70% isopropyl alcohol solution is used in conjunction with the LifeSite System for the localized cleansing of the access site (buttonhole), valve pocket and LifeSite valve.
Proposed Modification:	Modified indications for use to provide long-term, (chronic) access.

Device Description:
The LifeSite Hemodialysis Access System is a dialysis access device comprised of two separate valves and cannulas. One valve/cannula is used as the draw and the other valve/cannula is the return. The cannulas are placed in either the internal or external jugular or subclavian veins. They are manufactured from radiopaque silicone. The cannula ends connect to the valves, which are placed in a subcutaneous pocket. The valves are manufactured from titanium and stainless steel. When accessed with a 14-

gauge, fistula needle the valves internal pinch clamp opens allowing access to the vein via the cannula.

Summary of Data:
Simulated use testing of the LifeSite Valve was performed to provide information on the "life" of the device to ensure proper functionality over long-term use. LifeSite Valves were tested to 6000 actuations (approximately 38 years of use), using a 14-guage needle. After every 100 actuations leak testing was performed. All valves operated properly and no leaks were observed.

A clinical study was performed to ensure patient safety. Twenty-five of the sixty-seven patients in the alcohol trial were on dialysis using LifeSite for 12 months. This study has demonstrated that the LifeSite Hemodialysis Access System, when used in conjunction with 70% isopropyl alcohol, is safe for use in patients who require chronic (long-term) hemodiaylsis and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Nama Doddi, Ph.D.
Senior Vice President, Research & Development
VASCA, Inc.
3 Highwood Drive
TEWKSBURY MA 01876

Re: K023023
Trade/Device Name: LifeSite® Hemodialysis Access System, Model LHAS14120
LifeSite® Hemodialysis Cannula Exchange Kit, Model LHCEK0000
LifeSite® Insertion Kit, Model LSSK00120
LifeSite® Hemodialysis Access Cannula, Model LHAC12000
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: September 4, 2003
Received: September 5, 2003

Dear Dr. Doddi:

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

510(k) Number (if known): K023023

Device Name: LifeSite Hemodialysis Access System

Indications for Use:

The LifeSite Hemodialysis Access System provides fully implantable blood access for chronic (long term) hemodialysis. It is intended for use in patients who would otherwise be treated with standard cuffed hemodialysis catheters. A 70% isopropyl alcohol solution is used in conjunction with the LifeSite System for the localized cleansing of the access site (buttonhole), valve pocket and LifeSite valve.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023023