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510(k) SUMMARY FOR THE VASCA LIFESITE® HEMODIALYSIS ACCESS SYSTEM

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

A. Submitter's Information

Name:	Vasca, Inc.
Address:	3 Highwood Drive, Tewksbury, MA 01876
Phone:	(978) 863-4400
Fax:	(978) 863-4401
Contact Person:	Douglas E. Ferguson, Regulatory Affairs Manager
Date of Preparation:	May 25, 2000

B. Device Name:

Trade Name:	LifeSite Hemodialysis Access System
Common/Usual Name:	Blood Access Device and Accessories
Classification Name:	Blood Access Device and Accessories

C. Predicate Device Name(s):

Medcomp Tesio-Cath hemodialysis catheter, K821684
Bard Access Systems BardPort Titanium Implanted Port, K913235

D. Device Description/Indications for Use:

Description

The LifeSite Hemodialysis Access System consists of two primary components: (1) the LifeSite Hemodialysis Access Cannula, and (2) the LifeSite Hemodialysis Access Valve. The valve is surgically placed in a subcutaneous pocket. The cannula, placed into an internal jugular or subclavian vein, is connected to the valve by means of the barbed connector on the valve stem. Vascular access can be achieved by accessing the valve with a needle.

Accessories to the LifeSite Hemodialysis Access System, including a tunneler, introducer and Medisystems needle, will be packaged with the system and sold as a unit. Another accessory, the LifeSite Hemodialysis Cannula Exchange Kit will be sold separately.

Indications:
The LifeSite® Hemodialysis Access System provides fully-implantable blood access for patients who require hemodialysis while waiting for creation and/or maturation of permanent access. A 70% isopropyl alcohol solution is used in conjunction with the LifeSite System for the localized cleansing of the injection site, valve pocket, and LifeSite valve.

E. Technological Characteristics/Performance Data Summary

The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" decision tree (CDRH 510(k) Manual 92-4158) was utilized in conjunction with the technological characteristics and performance testing results to make a determination of substantial equivalence as follows:

1. **Does New Device Have Same Indication Statements?**

   No. While there are some differences in their specific indication statements, the LifeSite System and Tesio-Cath device have the same intended use. Both devices are intended for blood access for hemodialysis. The LifeSite System has a more narrow indication. The BardPort device also has the same intended use, for blood access. However, the BardPort device has the more specific indication of use for blood sampling and drug administration.

2. **Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect?**

   No. As stated previously, all three devices are intended to be used for blood access. In addition, both the LifeSite System and Tesio-Cath device are intended to be used for hemodialysis.

3. **Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?**

   No. Although there are some similarities, there are several technological characteristics which are different. For example, the mechanism to prevent blood flow when not in use is different for each device. There are also differences in physical dimensions.

4. **Could the New Characteristics Affect Safety or Effectiveness?**

   Yes. Changes to the mechanism to prevent blood flow could affect the ability of the device to prevent a leak. Physical changes may affect flow rate and other basic mechanical properties of the device, such as connection strength.

5. **Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**

   No. The types of safety and effectiveness questions remain the same. Ability to prevent leaks, provide adequate flow rates, and maintain high connection strength between the cannula and valve (for valve/port type devices) are safety and effectiveness concerns common to all blood access devices.

6. **Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?**

   Yes. The International Standards Organization has developed testing methods for assessing intravascular catheters and central venous catheters. The FDA has a guidance document outlining the testing to evaluate implanted infusion ports. These documents provide standard scientific methods for assessing the effects of the new characteristics on the device performance issues noted above.

7. **Are Performance Data Available to Assess Equivalence?**

   Yes. The LifeSite System was tested for safety and effectiveness. In Vitro tests were chosen and developed based on the October, 1990 FDA document "Guidance on 510(k) Submissions for Implanted Infusion Ports" and Parts 1 and 3 of the international standard ISO10555, "Sterile, single-use, intravascular catheters." Where appropriate, comparative testing was done using the Tesio-Cath device or a BardPort device; the devices used for comparison were chosen based on the presence of predicate design features relevant to the test.

   In addition, a prospective, randomized, multi-center clinical trial comparing efficacy of the Vasca LifeSite Hemodialysis Access System (as used with the cleansing solution, Clorpactin) to that of the Medcomp Tesio-Cath device was conducted. Clinical safety and efficacy data on the LifeSite System using isopropyl alcohol as the cleansing solution was

obtained in the continued access phase of the multi-center clinical trial and compared to that of the Tesio-Cath.

8. Do Performance Data Demonstrate Equivalence?

Yes. The performance of the LifeSite System was found to meet all clinically relevant acceptance criteria and was therefore acceptable. Where comparative testing was conducted, the LifeSite System performance was equivalent to or better than that of the relevant predicate device in every case or was acceptable based on clinically relevant criteria.

SUBSTANTIALLY EQUIVALENT DETERMINATION:

The Vasca LifeSite Hemodialysis Access System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Douglas E. Ferguson
Regulatory Affairs Manager
Vasca, Inc.
3 Highwood Drive
Tewksbury, Massachusetts 01876

Re: K001633
Vasca LifeSite® Hemodialysis Access System
Regulatory Class: III
21 CFR §876.5540/Procode: 78 MSD
Dated: May 25, 2000
Received: May 26, 2000

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

In addition, we have determined that your device kit contains a 70% isopropyl alcohol solution which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 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 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. INDICATIONS FOR USE

Device Name: Vasca LifeSite® Hemodialysis Access System

Indications for Use:

The LifeSite® Hemodialysis Access System provides fully-implantable blood access for patients who require hemodialysis while waiting for creation and/or maturation of permanent access. A 70% isopropyl alcohol solution is used in conjunction with the LifeSite System for the localized cleansing of the injection site, valve pocket, and LifeSite valve.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001633

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