MAR 2 3 2004

APPENDIX 6

K040634

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter Name:	Halkey-Roberts Corporation
Address:	11600 M. L. King Blvd., North St. Petersburg, FL 33716
Telephone Number:	727-577-1300
Fax Number:	727-578-0450
Contact Person:	John Sheldon
Date of Preparation	January 14, 2004

B. Device Name: Robertsite* Vial Adapter

Trade Name:	Robertsite* Vial Adapter
Common/Usual Name:	Medication Vial Adapter
Classification Name:	Intravascular Administration Set Accessory

C. Predicate Device Name: Robertsite* Needleless Injection site

Trade Name:	Swabable Luer Valve
Predicate Device name:	Alaris Smartsite® Needle-free Vial Access Device
Trade Name:	Vial Adapter with Smartsite®

D. Device Description:

Sterile single use device.

E. Intended Use:

Robertsite* Vial Adapter is indicated to allow multiple needleless access to injection medication vials for transfer or withdrawal of fluids from the vial.

F. Technological Characteristics Summary

1. Does the new device have the same indication statements?

Yes. The Robertsite* Vial Adapter has the same indication for use as the Alaris Smartsite® Needle Free Vial Access device. Both vial adapter systems are indicated for multiple needleless access to injection medication vials for transfer or withdrawal of fluids from the vial.

2. Does the new device have the same technological characteristics, e.g. Design, Materials, etc?

No. The stem and cap configuration of the Robertsite* Vial Adapter is different from that of the Alaris Smartsite® Needle-free Vial Access Device in the length of the device and the configuration of the split septum. The principles of operation are unchanged from the predicate comparison device.

3. Could the new characteristics affect safety or effectiveness?

Yes.

4. Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety and effectiveness questions are the same for all vial adapter systems.

5. Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's Draft October 12, 2000 "Guidance on 510(k) Submissions for Intravascular Administration Sets" and in house tests protocols were used to evaluate the device's performance.

6. Are performance data available to assess effects of new characteristics?

Yes.

7. Do performance data demonstrate equivalence?

Yes.

Based on FDA's decision tree, the Robertsite* Vial Adapter is substantially equivalent to the comparison predicate device, the Alaris Smartsite® Needle-free Vial Access Device system cleared for market on November 13, 2001 (K013087).

H. Performance Data

Testing was performed using the FDA's Draft October 12, 2000 "Guidance on 510(k) submissions for Intravascular Administration Sets" and in house protocol performance data gathered in design verification and validation testing demonstrated that the Robertsite* Vial Adapter is substantially equivalent to the predicate Alaris Smartsite® Needle-free Vial Access Device and /or met predetermined acceptance criteria, and the risks associated with use of the new device were found acceptable when evaluated by FMEA.

I. Clinical Performance Testing

Clinical performance testing was not required.

J. Conclusion

The Robertsite* Vial Adapter meets all the acceptance criteria of the testing performed and, based on FDA's decision tree, the Robertsite* Vial Adapter is substantially equivalent to the predicate device, the Alaris Smartsite® Needle-free Vial Access Device cleared for market on November 13, 2001 (K013087).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Halkey-Roberts Corporation
C/O Ms. Susan Grill
Responsible Third Party Official
Underwriter Laboratories, Incorporated
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K040634
Trade/Device Name: Robertsite* Vial Adapter Model 245700021
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 8, 2004
Received: March 10, 2004

Dear Ms. Grill:

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) 594-5618. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040634

INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: Robertsite* Vial Adapter

Indications for Use: Robertsite* Vial Adapter is indicated to allow multiple needleless access to an injection medication vial for the purpose of facilitating the withdrawal or addition of drugs/solutions from or to the vial.

(Please do not write below this line –continue on another page if needed)

Concurrence of Office of Device Evaluation

Prescription Use ✓ **OR** **Over – The – Counter Use**____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040634