**Halkey-Roberts**
An Atrion company

K061143

11600 Dr. Martin Luther King, Jr. Street North
St. Petersburg, FL 33716 USA
727-577-1300 / 800-303-4384
Fax 727-578-0450

January 31, 2006

Food and Drug Administration,
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850.

MAY 10 2006

**510(k) SUMMARY**

On behalf of Halkey-Roberts Corporation,

Contact: Gordon Hicks, QA/RA Director
Address: 11600 Dr. Martin Luther King, Jr. St. N.
St. Petersburg, FL 33716
Phone (727) 577-1300 / (800) 303-4384 Ext. 224

Date of Summary Preparation: January 31, 2006

Device Name:
Tradename: Robertsite® Stopcock
Common name: IV set stopcock
Classification Name: Intravascular Administration Set Accessory

Legally Marketed Substantially Equivalent Devices:
Med-Net Stopcock (K955782)
Robertsite® Needleless Injection Site (K002689)
Robertsite® Vial Adapter (K040634)

Description of Device:
The device is a single use 4-way stopcock with one Robertsite® needleless injection port. The major device materials are polycarbonate and silicone.

Intended Use:
The Robertsite® 4-way stopcock provides a needleless access port and multi-directional flow during fluid administration to a patient's vascular system.

Technological Characteristics of device:
The new device's technological characteristics are similar to the predicate devices in materials and design. Features from the predicate devices have been combined to produce an integrated needleless connection to allow needleless IV access to a stopcock. The performance testing did not raise new types of safety or effectiveness questions. The new device was tested according to the *15 April, 2005 FDA Guidance for Intravascular Administration Sets* and the *ISO 8536-10:2004 – Infusion equipment for medical use – Accessories for fluid lines for use with pressure infusion equipment* - international standard and in-house protocols. Test data demonstrate that the new device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

Halkey-Roberts Corporation
C/O Mr. Jeffrey D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle, North Carolina 27709

Re: K061143
Trade/Device Name: Robertsite® 4-Way Stopcock
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: April 21, 2006
Received: April 25, 2006

Dear Mr. Rongero:

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.

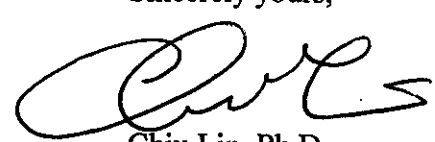
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.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

# Indications for Use

**510(k) Number (if known):** K961143

**Device Name:** Robertsite® 4-Way Stopcock

**Indications for Use:** The Robertsite® stopcock provides a needleless access port and multi-directional flow during fluid administration to a patient's vascular system.

| Prescription Use | ✓ | AND / OR | Over-The-Counter-Use | |
|---|---|---|---|---|
| (Part 21 CFR 801 Subpart D) | | | (Part 21 CFR 801 Subpart C) | |

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K961143