SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health, Alaris® Products®

SMARTSITE® STOPCOCK

DEC 1 4 2007

SUBMITTER INFORMATION

A.	Company Name:	Cardinal Health, Alaris® Products
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2733
C.	Company Phone: Company Fax:	(858) 617-5889 (858) 617-5960
D.	Contact Person:	Stacy L. Lewis Principal Regulatory Affairs Specialist Cardinal Health, Alaris® Products
E.	Date Summary Prepared:	December 12, 2007

DEVICE IDENTIFICATION

A.	Generic Device Name:	Stopcock
B.	Trade/Proprietary Name:	SmartSite® Stopcock
C.	Classification:	Class II
D.	Product Code:	FMG, Stopcock, IV Administration Set

DEVICE DESCRIPTION

The SmartSite® Stopcock is a single use 4-way stopcock with an integrated SmartSite® needle free valve on the side port. Arrows on the handle point to the direction of flow. The side port consists of a SmartSite® needle free valve that provides closed, needle-free access that seals upon removal and does not require re-capping between uses.

SUMMARY OF SAFETY AND EFFECTIVENESS
Cardinal Health, Alaris® Products
SMARTSITE® STOPCOCK
Page 2 of 3

DEVICE DESCRIPTION (Continued)

The SmartSite® Stopcock share similar characteristics and will operate the same as currently marketed stopcocks, as an accessory to an IV administration set that regulates the directional flow to a patient's vascular system and provides an access port(s) for the administration of solutions.

SUBSTANTIAL EQUIVALENCE

The Cardinal Health, Alaris® Products SmartSite® Stopcock is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Elcam Closed Swabbable Stopcock	Elcam Medical	K060231	04/13/06
SmartSite® Needle Free Valve	Cardinal Health, Alaris Products	K960280	04/04/96

INTENDED USE

The SmartSite® Stopcock is indicated for fluid flow, directional control and for providing access port(s) for administration of solutions and blood products. Typical uses include pressure monitoring, intravenous fluid administration and transfusion. The SmartSite® valve port allows the user to access the primary line without the use of a needle.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the SmartSite® Stopcock and the predicate devices has been performed. The results of this comparison demonstrate that the SmartSite® Stopcock is equivalent to the marketed predicate devices in technological characteristics.

SUMMARY OF SAFETY AND EFFECTIVENESS
Cardinal Health, Alaris® Products
SMARTSITE® STOPCOCK

PERFORMANCE DATA

The performance data indicate that the SmartSite® Stopcock meets specified requirements and 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

DEC 1 4 2007

Ms. Stacy L. Lewis
Principal Regulatory Affairs Specialist
Cardinal Health, Alaris Products
10020 Pacific Mesa Boulevard
San Diego, California 92121-2772

Re: K071400
Trade/Device Name: SmartSite® StopCock
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: November 27, 2007
Received: November 28, 2007

Dear Ms. Lewis:

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) 276-00115. 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,

Anthony D. Watson for

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

ATTACHMENT A

INDICATIONS FOR USE

510(k) Number: K071400

Device Trade Name: SmartSite® Stopcock

Indications For Use:

The SmartSite® Stopcock is indicated for fluid flow, directional control and for providing access port(s) for administration of solutions and blood products. Typical uses include pressure monitoring, intravenous fluid administration and transfusion. The SmartSite® valve port allows the user to access the primary line without the use of a needle.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K071400