SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 26 2006

Cardinal Health 303, Inc.
DBA Cardinal Health, Alaris® Products

SmartSite Valve Sets with Additional Indication

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) 458-7830 (858) 458-6114
D.	Contact Person:	Stacy L. Lewis Sr. Regulatory Affairs Specialist
E.	Date Summary Prepared:	May 5, 2006

DEVICE IDENTIFICATION

A.	Generic Device Name:	Administration Set
B.	Trade/Proprietary Name:	SmartSite Needle Free Valve Administration Sets
C.	Classification:	Class II
D.	Product Code:	FPA, Intravascular Administration Set

DEVICE DESCRIPTION

As originally submitted, the SmartSite Administration Sets (K960280) are intended to be used for IV administration of drugs and fluids, and the specific purpose for the SmartSite Valve is to allow the user to add drugs and fluids into the primary line without the use of a needle. This Traditional 510(k) Premarket Notification will add a new indication for the SmartSite Valve and qualified extension sets to allow use with low pressure devices up to 325psi. When used with a low pressure power injector, the SmartSite Valve must be secured to other devices with a luer lock connection and the other devices must also be rated for up to 325 psi. This new indication will require no changes to the current device design, materials, manufacturing processes, method of operation or basic scientific technology.

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SUBSTANTIAL EQUIVALENCE

The Cardinal Health, Alaris Products SmartSite Valve Sets with Additional Indication is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
SmartSite Administration Sets	Cardinal Health, Alaris Products	K960280	April 4, 1996

INTENDED USE

The intended use for the SmartSite Valve and sets is to allow IV fluid delivery of a wide range of fluids. The needle free valve allows the user to add medication into the primary line without the use of a needle. This new indication will allow the SmartSite Valve and qualified sets to also be used with low pressure power injectors for which the maximum pressure setting is 325 psi. When used with a power injector, the SmartSite Valve must be secured to other devices with a luer lock connection; other devices must also be rated for up to 325 psi.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Cardinal Health, Alaris Products SmartSite Valve Administration Sets with Additional Indication and the predicate devices has been performed. The results of this comparison demonstrate that the SmartSite Valve Sets with Additional Indication is equivalent to the marketed predicate device in technological characteristics.

PERFORMANCE DATA

The performance data indicate that the Cardinal Health, Alaris Products SmartSite Sets with Additional Indication meets specified requirements 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

JUL 26 2006

Ms. Stacy L. Lewis
Sr. Regulatory Affairs Specialist
Cardinal Health, Alaris® Products
10221 Wateridge Circle
San Diego, California 92121-2733

Re: K061285
Trade/Device Name: SmartSite Needle Free Valve Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 6, 2006
Received: May 8, 2006

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.

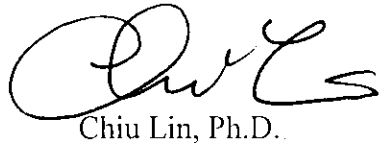
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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 (240) 276-3150 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: K061285 (To Be Assigned By FDA)

Device Trade Name: SmartSite Needle Free Valve Administration Sets

Indications For Use:

The SmartSite Needle Free Valve Administration Sets are intended for use in today's growing professional healthcare environment including healthcare facilities, home care, and medical transport that utilize infusion systems for the delivery of fluids, medications, blood and blood products. The SmartSite valve allows the user to add medication into the primary line without the use of a needle. The SmartSite valve may also be used with low pressure power injectors rated for a maximum setting of 325psi.

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)

Anthony D. Watson

...n Sign-Off)
...n of Anesthesiology, General Hospi...
...ion Control, Dental Devices

K061285