K050115

APR - 1 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

Cardinal Health, Alaris Products

Blood Hand Pump Set

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 Cardinal Health, Alaris Products
E.	Date Summary Prepared:	March 16, 2005

DEVICE IDENTIFICATION

A.	Generic Device Name:	Blood Administration Set
B.	Trade/Proprietary Name:	Blood Hand Pump Set
C.	Classification:	Class II
D.	Product Code:	BRZ, Blood Transfusion Set

DEVICE DESCRIPTION

The Blood Hand Pump Administration Set is a single use, disposable, gravity blood set with a blood filter and hand pressure pump. The addition of the hand pressure pump provides the capability for delivering blood/blood products more rapidly by compressing the pump by hand. Blood sets with hand pressure pumps are typically used by healthcare professionals in clinical settings, including emergency rooms, intensive care units, operating rooms, surgery centers, trauma centers, and pre-hospital transport. Using a hand pump set increases the flow rate and helps ensure timely delivery.

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Blood Hand Pump Set
Page 2 of 2

SUBSTANTIAL EQUIVALENCE

The Cardinal Health, Alaris Products Blood Hand Pump Administration Set is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
ALARIS Blood Administration Set	Cardinal Health, Alaris Products	K882302	7/12/1988
Baxter Fenwal Y-Type Blood/Solution Set	Baxter Corporation	K881321	6/16/1998

INTENDED USE

The Blood Hand Pump Set will be used for patients that require blood. The set can be used by gravity flow or with hand pump compressions, depending on how quickly blood delivery is needed. It is intended for use by healthcare professionals (including nurses, doctors, emergency technicians, etc.) in clinical environments. The flow rate for hand pump compression administration may be as much as twice that of gravity flow.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Cardinal Health, Alaris Products Blood Hand Pump Set and the predicate devices has been performed. The results of this comparison demonstrate that the Blood Hand Pump Set is equivalent to the marketed predicate devices in technological characteristics.

PERFORMANCE DATA

The performance data indicate that the Cardinal Health, Alaris Products Blood Hand Pump Set 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

APR - 1 2005

Ms. Stacy L. Lewis
Senior Regulatory Affairs Specialist
Cardinal Health, Alaris Products
10221 Wateridge Circle
San Diego, California 92121-2772

Re: K050115
Trade/Device Name: Blood Hand Pump Administration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: BRZ
Dated: January 17, 2005
Received: January 18, 2005

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 (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: K050115 (To Be Assigned By FDA)

Device Trade Name: Blood Hand Pump Administration Set

Indications For Use:

A single use, disposable, blood administration set with pressure pump and blood filter used to deliver blood/blood products rapidly through use of the pressure pump and/or gravity flow.

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)

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

(510(k) Number: K050115