# SUMMARY OF SAFETY AND EFFECTIVENESS

## Cardinal Health, Alaris® Products®

K071108

## TEXIUM™ SYRINGE

MAY 24 2007

## SUBMITTER INFORMATION

| | | |
|---|---|---|
| A. | Company Name: | Cardinal Health, Alaris® Products |
| B. | Company Address: | 10221 Wateridge Circle<br>San Diego, CA 92121-2733 |
| C. | Company Phone:<br>Company Fax: | (858) 458-7830<br>(858) 458-6114 |
| D. | Contact Person: | Stacy L. Lewis<br>Principal Regulatory Affairs Specialist<br>Cardinal Health, Alaris® Products |
| E. | Date Summary Prepared: | April 18, 2007 |

## DEVICE IDENTIFICATION

| | | |
|---|---|---|
| A. | Generic Device Name: | Intravascular Administration Set |
| B. | Trade/Proprietary Name: | Texium™ Syringe |
| C. | Classification: | Class II |
| D. | Product Code: | FMF, Piston Syringe |

## DEVICE DESCRIPTION

The Texium™ Syringe is a single use piston syringe that consists of a syringe (3mL, 5mL, 10mL, 20mL or 60mL) ***permanently*** bonded to a closed male luer device (Texium™ Closed Male Luer, K053049). The Texium™ Syringe is designed to promote safe handling of fluids and medications, particularly hazardous or cytotoxic drugs. Leakage of drug into the environments is effectively avoided during all phases of drug handling when the Texium™ Syringe is used in conjunction with the SmartSite® Needle Free Valve port: the preparation of the drug, the administration of the drug to the patient, and waste handling. The Texium™ Syringe is a passive device – it requires no cap and automatically seals upon disconnection.

**SUMMARY OF SAFETY AND EFFECTIVENESS**
**Cardinal Health, Alaris® Products**
**TEXIUM™ SYRINGE**
**Page 2 of 2**

K071108

## SUBSTANTIAL EQUIVALENCE

The Cardinal Health, Texium™ Syringe is of comparable type and is substantially equivalent to the following predicate devices:

| Predicate Device | Manufacturer | 510(k) No. | Date Cleared |
|---|---|---|---|
| Texium™ Closed Male Luer (originally submitted as the Alaris® Safety Male Luer | Cardinal Health, Alaris® Products | K053049 | 1/12/06 |
| Becton Dickinson Syringe | Becton Dickinson & Company | K954064 | 11/21/95 |

## INTENDED USE

The Texium™ Syringe is intended to provide leak-free handling of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, during all three phases of drug handling when the Texium™ Syringe is used in conjunction with the SmartSite® Needle Free Valve port: the preparation of the drug, the administration of the drug to the patient, and waste handling. The Texium™ Syringe is intended to reduce environmental surface contamination of the work area.

## TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Texium™ Syringe and the predicate devices has been performed. The results of this comparison demonstrate that the Texium™ Syringe is equivalent to the marketed predicate devices in technological characteristics.

## PERFORMANCE DATA

The performance data indicate that the Texium™ Syringe 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

MAY 24 2007

Ms. Stacy L. Lewis
Principal Regulatory Affairs Specialist
Cardinal Health, Alaris Products
10221 Wateride Circle
San Diego, California 92121

Re: K071108
Trade/Device Name: Texium™ Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 18, 2007
Received: April 19, 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) 276-0115. 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: K071108 (To Be Assigned By FDA)

Device Trade Name: Texium™ Syringe

**Indications for Use:**

The Texium™ Syringe is indicated for use by healthcare professionals for fluid aspiration/injection, reconstituting, dispensing/ transferring, administering, and disposal of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, as well as non-hazardous fluids. The Texium™ Syringe is intended for use with the SmartSite® Needle Free Valve port or standard open female luers.

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)

(Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...(k) Number: K071108