K121182

# 5. 510(k) Summary

MAY - 3 2012

## 5.1. Submitter Information

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**Date Summary Prepared:** December 6, 2011

## 5.2. Device Identification

**Trade/Proprietary Name:** ViaLok™ Non-vented

**Common Name:** Vial Access Device

**Classification Name:** Intravascular Administration Set
21 CFR 880.5440, Class II

**Classification Panel** General Hospital
**Product Code:** LHI, I.V. Fluid Transfer Set

## 5.3. Predicate Device

The ViaLok™ is substantially equivalent to the following predicate device:

| Device | Manufacturer | 510(k) | Date Cleared |
|---|---|---|---|
| Single Dose Dispensing Pin | ALARIS Medical Systems, Inc. | K013087 | November 13, 2001 |

## 5.4. Device Description

The ViaLok™ Non-vented (ViaLok™) is a sterile, stand-alone, single-use, disposable device which permits access to a medication vial without the use of a needle. The ViaLok™ is inserted into a stopper of a medication vial. The healthcare provided uses the ViaLok™ to inject or withdrawal fluid from the vial. The ViaLok™ includes four product configurations in this submission:

- ViaLok™ Non-vented, 20mm with female luer
- ViaLok™ Non-vented, 20mm with male luer
- ViaLok™ Non-vented, 13mm with female luer
- ViaLok™ Non-vented, 13mm with male luer

The ViaLok™ is offered in two sizes; 20mm and 13mm. The ViaLok™ is configured to mate with standard medication vial enclosure sizes (20mm and 13mm). Each ViaLok™ size configuration is offered in female and male luer versions.

## 5.5. Intended Use

The ViaLok™ is a stand-alone, single-use, disposable device which permits access to a medication vial without the use of a needle. The device is intended for use by healthcare professionals in a wide variety of healthcare environments, including hospitals, healthcare facilities, and pharmacies.

The ViaLok™ is indicated for use with standard medication vials and mating luer access devices for withdrawal and/or injection of fluid.

The indications statement for the ViaLok™ differs from the indications statement of the predicate device (presented in 510k K013087) in that the ViaLok™ calls out that the device is used with "mating luer access devices for withdrawal and/or injection of fluid". The Single Dose Dispensing Pin refers to a specific type of mating luer access device by stating that it is used with "needleless syringes for withdrawal and/or injection of fluid". The ViaLok™ uses the term "mating luer access device" because the ViaLok™ is offered in both male and female luer. Mating luer access devices are therefore not limited to syringes. This difference does not affect the ability of users to use the devices safely and effectively.

## 5.6. Predicate Device Comparison – Technical Characteristics

A direct comparison of the technical characteristics of the ViaLok™ and the predicate device, ALARIS Medical Systems, Inc. Single Dose Dispensing Pin (K013087), demonstrates equivalency. The ViaLok™ device is made up of a spike, luer access and a shroud. The Single Dose Dispensing Pin is made up of a spike and luer access. The spike is used to penetrate a standard medication vial stopper and provide a fluid path.

The purpose of the ViaLok™ shroud is to secure the device to a standard medication vial after the stopper is penetrated. The ViaLok™ shroud is considered a minor characteristic difference from the predicate device and does not introduce any new safety or efficacy concerns.

The Single Dose Dispensing Pin can be used with standard medication vials containing a stopper enclosure. The ViaLok™ offers a product configuration compatible with the 13mm and a product configuration compatible with 20mm standard medication vials containing a stopper enclosure.

The ViaLok™ is molded methyl methacrylate acrylonitrile butadiene styrene copolymer (MABS). The ViaLok™ may be provided with a cap which is molded from a low density polyethylene (female luer) or a high density polyethylene (male luer). The ViaLok™ and protective caps do not contain natural rubber latex.

The ViaLok™ has been tested and meets the biological requirements outlined in ISO 10993-1, ISO 10993-4, ISO 10993-5, ISO 10993-9, ISO 10993-10, and ISO 10993-11. A summary of these test results is provided in Section 15 – Biocompatibility.

The material content of the predicate device (Single Dose Dispensing Pin) is unknown.

## 5.7. Predicate Device Comparison – Performance Characteristics

The performance data supplied in this submission demonstrates that the ViaLok™ meets all specified requirements and is substantially equivalent to the predicate device.

Performance data for the predicate device (ALARIS Medical Systems, Inc. Single Dose Dispensing Pin) was not available. Therefore, samples of the predicate device were tested along with the ViaLok™.

The following tests were conducted on the ViaLok™ and Single Dose Dispensing Pin to demonstrate equivalency of the performance characteristics:

- Attachment Force
- Flow Rate

- Pressurization Leak Test
- Vacuum Leak Test
- Luer Leakage (Air Ingress)
- Luer Leakage (Fluid Ingress)
- Priming Volume
- Detachment Force
- ISO 594-2 Test Methods (ViaLok™ tested only)
    - Luer Leakage (Air Ingress)
    - Luer Leakage (Fluid Ingress)
    - Luer Attachment
    - Luer Separation Force
    - Unscrewing Torque
    - Resistance to Overriding
    - Stress Cracking
- Biocompatibility - ISO 10993 (ViaLok™ tested only)
    - Cytotoxicity by Elution Test (Cytotoxicity)
    - Intracutaneous Reactivity (Irritation or Intracutaneous Reactivity)
    - Maximization Test for Delayed Hypersensivity (Sensitization)
    - Acute Systemic Toxicity (Systemic Toxicity (Acute))
    - Evaluation of Hemocompatibility : Interaction with Blood (Hemocompatibility)

Test results demonstrated that the ViaLok™ is as effective, and performs at least as safely and effectively as the legally marketed device (ALARIS Medical Systems, Inc. Single Dose Dispensing Pin).

## 5.8. Conclusion

Based on comparisons of the device's intended use, technology and performance characteristics, the ViaLok™ is substantially equivalent to the indicated predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Yukon Medical, LLC
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services. LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

MAY - 3 2012

Re: K121182
Trade/Device Name: ViaLok™
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: April 17, 2012
Received: April 18, 2012

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. Indications for Use Statement

510(k) Number (if known): K121182

Device Name: ViaLok™

Indications for Use: The ViaLok™ is a stand-alone, single-use, disposable device which permits access to a medication vial without the use of a needle. The device is intended for use by healthcare professionals in a wide variety of healthcare environments, including hospitals, healthcare facilities, and pharmacies.

The ViaLok™ is indicated for use with standard medication vials and mating luer access devices for withdrawal and/or injection of fluid.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K121182