

K 12 2265

5. 510(k) Summary

5.1. Submitter Information

AUG 14 2012

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Date Summary Prepared: June 29, 2012

5.2. Device Identification

Trade/Proprietary Name: ViaLok™ 20 mm Single Vial Access Device,
Vented, Female Luer

ViaLok™ 13 mm Single Vial Access Device,
Vented, Female Luer

Universal Single Vial Access Device, Vented,
Female Luer

Common Name: Vial Access Device

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

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

5.3. Predicate Device

The Vented Single Vial Access Device is substantially equivalent to the following predicate device:

Device	Manufacturer	510(k)	Date Cleared
ViaLok™ Non-vented	Yukon Medical	K121182	May 3, 2012
Vented Vial Adapter Transfer Device	Medimop Medical Projects, LTD.	K062482	November 3, 2006

5.4. Device Description

The Vented Single Vial Access Device (ViaLok™ / Universal) is a sterile, stand-alone, single-use, disposable device which permits access to a medication vial without the use of a needle. These devices are inserted into a stopper of a medication vial. The healthcare provider uses the Vented Single Vial Access Device to transfer and mix drugs contained in standard medication vials. The Vented Single Vial Access Device includes three product configurations in this submission:

- ViaLok™ 20 mm Single Vial Access Device, Vented, Female Luer
- ViaLok™ 13 mm Single Vial Access Device, Vented, Female Luer
- Universal Single Vial Access Device, Vented, Female Luer

The 20mm and 13mm product configurations are intended to mate with standard medication vial enclosure sizes (20mm and 13mm, respectively). The Universal device does not contain a shroud and can be used independent of enclosure size. Each Vented Single Vial Access Device configuration is offered with a female luer.

5.5. Intended Use

The Vented Single Vial Access Device 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 Vented Single Vial Access Device 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 Vented Single Vial Access Device is the same as its predicate device, Yukon Medical's ViaLok™ Non-vented (K121182).

5.6. Predicate Device Comparison – Technical Characteristics

Equivalency of technical characteristics is demonstrated through a direct comparison of the Vented Single Vial Access Device and the predicate devices listed in the table below.

Technical Characteristic	Device		
	Subject Device: Vented Single Vial Access Device	Predicate: ViaLok™ Non-vented (K121182)	Predicate: Vented Vial Adapter Transfer Device (K062482)
Spike	Yes	Yes	Yes
Shroud	20mm and 13mm – Yes Universal - No	Yes	Yes
Luer Access	Yes	Yes	Yes
Filter	Yes	No	Yes

Spike

The spike is used to penetrate a standard medication vial stopper and provide fluid and filtered air paths.

The subject device and the predicate (Vented Vial Adapter Transfer Device) both have equivalent dual lumen spikes; one lumen for fluid transfer and the other which allows for pressure equalization with vented air.

Shroud

The purpose of the shroud is to secure the device to a standard medication vial after the stopper is penetrated. The 20mm and 13mm product configurations contain this feature which is equivalent to that of the ViaLok™ Non-vented design.

Luer Access

All configurations of the subject device facilitate connection of mating luer access devices. This is equivalent to referenced predicate devices.

Filter

Air flows into and out of the vial through a filter during drug transfer/withdrawal.

The subject device and the predicate (Vented Vial Adapter Transfer Device) both provide equivalent means of air filtration.

Materials

The Vented Single Vial Access Device is an assembly of a molded methyl methacrylate acrylonitrile butadiene styrene copolymer (MABS) body and filter sub-assembly. The filter sub-assembly is comprised of a non-woven nylon substrate secured to a molded polyethylene housing.

The Vented Single Vial Access Device may be provided with a molded polyethylene cap and/or a molded polyethylene spike cover.

The subject device's spike may also be lubricated with a fluorosilicone polymer.

The Vented Single Vial Access Device materials do not contain natural rubber latex.

The Vented Single Vial Access Device 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.

5.7. Predicate Device Comparison – Performance Characteristics

The performance data supplied with this submission demonstrates that the Vented Single Vial Access Device meets all specified requirements and is substantially equivalent to the predicate device(s).

Performance data for the Vented Vial Adapter Transfer Device was not available. Therefore, samples of the predicate device were tested along with the Vented Single Vial Access Device.

The following tests were conducted on the Vented Single Vial Access Device to demonstrate equivalency of the performance characteristics to the predicate device(s):

- Attachment Force
- Flow Rate
- Pressurization Leak Test
- Vacuum Leak Test
- Priming Volume
- Detachment Force
- Filter Integrity
- Septum Coring
- Multiple Access

- ISO 594-2 Test Methods (Vented Single Vial Access Device 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 (Vented Single Vial Access Device tested only)
 - Cytotoxicity by Elution Test (Cytotoxicity)
 - Intracutaneous Reactivity (Irritation or Intracutaneous Reactivity)
 - Maximization Test for Delayed Hypersensitivity (Sensitization)
 - Acute Systemic Toxicity (Systemic Toxicity (Acute))
 - Evaluation of Hemocompatibility: Interaction with Blood (Hemocompatibility)

Test results demonstrate that the Vented Single Vial Access Device is as safe and effective as the legally marketed devices designated as predicate device(s).

5.8. Conclusion

Test results demonstrate that the Vented Single Vial Access Device is as effective, and performs at least as safely and effectively as the legally marketed devices designated as predicate devices.

Based on comparisons of the device's intended use, technology and performance characteristics, the Vented Single Vial Access Device is substantially equivalent to the indicated predicate devices.

Any differences between the Vented Single Vial Access Device and the equivalent predicate devices have no significant influence on safety or effectiveness.



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Document Control Room - WO66-G609
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Yukon Medical, Limited Liability Company
C/O Mark Job
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AUG 14 2012

Re: K122265

Trade/Device Name: ViaLok™ 20 mm Single Vial Access Device, Vented,
Female Luer
ViaLok™ 13 mm Single Vial Access Device, Vented,
Female Luer
Universal Single Vial Access Device, Vented, Female Luer

Regulation Number: 21 CFR 880.5440

Regulation Name: Intravascular Administration Set

Regulatory Class: II

Product Code: LHI

Dated: July 27, 2012

Received: July 30, 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

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addition, FDA may publish further announcements concerning your device in the Federal Register.

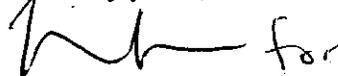
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K122265

Device Name:

- ViaLok™ 20 mm Single Vial Access Device, Vented, Female Luer
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Indications for Use: The Vented Single Vial Access Device 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 Vented Single Vial Access Device is indicated for use with standard medication vials and mating luer access devices for withdrawal and/or injection of fluid.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert C. Chagnon 8/13/12

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122265