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K472511 (P. 1 of 2)

510(k) summary for the SWABABLE VIAL ADAPTER
 (as required by section 807.92)

510(k) Notification submitted by: Medimop Medical Projects Ltd.
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DEC 13 2007

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Contact person: Nachum Naveh
 Manager, Quality Assurance and Regulatory Affairs

Date Summary Prepared August 24, 2007

Trade Name: Swabable Vial Adapter

Classification name: General Hospital Class II, 80LHI
 Per 21 CFR 880.5440 Intravascular administration set

Common device name: Same as Trade name

Predicate devices: ROBERTSITE VIAL ADAPTER
 510(k) No. K040634
 Halkey-Roberts

SMARTSITE VENTED VIAL ACCESS DEVICE
 510(k) No. K052790
 Cardinal Healthcare – Alaris Products

Manufacturer: Medimop Medical Projects Ltd.
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K472511 (P. 20A2)

Material:

The Swabable Vial Adapter is composed of materials that were tested in accordance with the ISO 10993-1 standard and/or USP VI requirements and were determined suitable for the Indications for Use of this product.

Device Description:

The Swabable Vial Adapter is designed for the purpose of allowing safe and easy transfer of liquid drugs from and into vials. The product allows quick transfer of the contents of a syringe, typically containing diluents, into a drug (in the form of powder) vial and easy aspiration of the dissolved drug back into a syringe, or any other standard accessory.

The Swabable Vial Adapter is an assembly of three components. A Hydrophobic medium (optional) is attached to the "body" with the double lumen spike (penetrating the rubber stopper) and a cap (with a luer connection) is attached to the sub-assembly.

Indications for Use:

The Swabable Vial Adapter is indicated to allow multiple needleless accesses to an injection medication vial for the purpose of facilitating the withdrawal or addition of drugs/solutions from or to the vial

Technological comparison to Predicate Device:

The Swabable Vial Adapter has Indications for Use identical to the Robertsite Vial Adapter and similar to the Smartsite Vented Vial Access Device– all are intended for transferring and mixing drugs and diluents contained in vials. All products have multiple access valves and piercing spikes, which enable the users to create a direct passage to and from vials, in a sterile manner.

The Swabable Vial Adapter allows the connection any standard accessory with a luer connection to be connected to a vial. Once mixing of the diluent and the drug is complete the drug solution is ready for use and may be aspirated into an accessory (e.g. syringe). This can be repeated until the contents of the vial are fully removed. The adapter vial assembly is a single use device and should be disposed of after use.

All devices are packaged sterile and designed ergonomically.

Any differences between the Swabable Vial Adapter solution and the equivalent devices have no significant influence on safety or effectiveness.

Safety and Effectiveness:

All finished products are tested and must meet all required release specifications prior to distribution. The array of testing required for release include but are not limited to; Physical testing, visual examination (in-process and finished product).

Conclusion:

It is our conclusion that the Swabable Vial Adapter and its predicates are substantially equivalent in their Indications for Use, design, material, sterility and packaging.

The Swabable Vial Adapter is to be used in a similar manner to the predicate devices and introduces no new issues of safety and effectiveness.



DEC 13 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medimop Medical Projects, Limited
C/O Mr. Ari Y. Sobel
Director, Regulatory Affairs
West Pharmaceutical Services
101 Gordon Drive
Lionville, Pennsylvania 19341

Re: K072511

Trade/Device Name: Swabable Vial Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: December 6, 2007
Received: December 7, 2007

Dear Mr. Sobel:

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 (if known): K072511

Device Name: Swabable Vial Adapter

Indications for Use: The Swabable Vial Adapter is indicated to allow multiple needleless accesses to an injection medication vial for the purpose of facilitating the withdrawal or addition of drugs/solutions from or to the vial



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

510(k) Number: K47 2511

Prescription Use (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)

Concurrence of CDRH, Office of Device Evaluation (ODE)