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SEP 24 2007



מגדה תעשיות ציוד רפואי  
מדיקל

**510(k) Summary:**

**TEVADAPTOR™, Closed Drug Reconstitution and Transfer System**

**Company Name:**  
Migada Plant

**Contact Person:**

Yossi Shachar  
QA/RA Manager  
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**US Agent:**

Mr. John Riggi  
Donawa Consulting  
152 Schimwood Court  
Getzville, NY 14608  
Phone: (716) 688 0543

**Date prepared:** June 10, 2007

**Trade Name:**

TEVADAPTOR™, Closed Drug Reconstitution and Transfer System

**Common/usual name:** Closed Drug reconstitution system

**Classification name:** Set, IV Fluid Transfer

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A MEMBER OF  
**TEVA GROUP**

מקבוצת

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מיגדה תעשיית ציוד רפואי

**Product Code:** LHI

**Regulation No.:** 880.5440

**Class:** II

**Panel identification:** General Hospital Panel

**Predicate Device:**

PhaSeal® closed system for the preparation and administration of parenteral drugs, Carmel Pharma AB, S-402 28 Gottingen, Sweden, cleared under 510(k) no. K980381.

**Description of the device:**

The device comprises of the following components:

- Vial Adaptor System with 13 mm Vial converter
- Syringe Adaptor System
- Connecting Set
- Spike Port Adaptor
- Luer Lock Adaptor

The Vial Adaptor System is intended to fit over vials with 20mm caps. A converter accessory enables the use of the Vial Adaptor System with a 13 mm cap vial. A special venting mechanism ensures automatic, sterile, pressure equalization within the vial, preventing drug particle and aerosol escape into the environment. The Vial Adaptor is also effective when used with Radionuclide drugs. A special charcoal layer within the venting system prevents also drug vapor from escaping, ensuring the system is closed to all toxic species. The air entering the vial is sterile due to this combination of filters. An elastomeric, non-latex septum is designed for connection of the Syringe Adaptor System for introduction or withdrawal of liquid. The interface for connecting with the Syringe Adaptor is designed so that it can be easily cleaned and disinfected when required.

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The Syringe Adaptor System is intended for connection to a standard luer lock syringe. A special non-latex elastomer protector covers the liquid dispensing needle tip. A clamp mechanism reversibly connects the Syringe Adaptor System to the other components. The design incorporates a Passive-Needle protection that eliminates chances of needle-stick injuries.

The Spike Port Adaptor is intended for connection to the spike port of an infusion bag. A non-latex septum enables connection to the Syringe Adaptor System for withdrawal of diluents or introduction of drug. Capped short tubing enables connection of the drug containing bag to a delivery set in the hospital ward.

The Connecting set is similar to the Spike Port Adaptor, except for a female luer lock connection at the distal end.

The Luer Lock Adaptor enables the connection of the Syringe Adaptor System to an intravenous infusion line for direct drug injection.

**Intended Use:**

The TEVADAPTOR™, Closed Drug Reconstitution and Transfer System is a closed system to be used by pharmacists or other healthcare professionals to prepare drugs, including cytotoxic drugs, for intravenous infusion or injection.

**Substantial Equivalence:**

The TEVADAPTOR™, Closed Drug Reconstitution and Transfer System has the same intended use as the PhaSeal® closed system for the preparation and administration of parenteral drugs, cleared under 510(k) no. K980381 and has equivalent performance characteristics. It is therefore substantially equivalent to that device.

**Conclusion -**

The evaluation of the TEVADAPTOR™, Closed Drug Reconstitution and Transfer System does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.



SEP 24 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Yossi Shachar  
Quality Assurance/Regulatory Affairs Manager  
Migada Plant  
North Industrial Zone  
P.O. Box 888  
Kiryat Shmona, 10258  
ISRAEL

Re: K071741  
Trade/Device Name: TEVADAPTOR™, Closed Drug Reconstitution and Transfer  
System  
Regulation Number: 21 CFR 880.5540  
Regulation Name: Set, IV Fluid Transfer  
Regulatory Class: II  
Product Code: LHI  
Dated: June 25, 2007  
Received: June 27, 2007

Dear Mr. Shachar:

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):           K071741          

Device Name:           TEVADAPTOR™, Closed Drug Reconstitution and Transfer System

Indications for Use:    The TEVADAPTOR™, Closed Drug Reconstitution and Transfer System is a closed system to be used by pharmacists or other healthcare professionals to prepare drugs, including cytotoxic drugs, for intravenous infusion or injection.

Prescription Use   X      OR  
(Part 21 CFR 801 Subpart D)

Over the Counter Use             
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE):

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

510(k) Number:           K071741