Plastmed
A MEDICAL DEVICE COMPANY

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K091389

Section 14 – SPECIAL 510(K) SUMMARY

OCT 22 2009

SPECIAL 510(K) SUMMARY

EQUASHIELD™ Luer Lock Connector Pair

510(k) Number K091389

Applicant's Name: Plastmed Ltd.
Tefen Industrial Park
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Contact Person: Elissa Burg
Tefen Industrial Park
P.O.B 26, ISRAEL , 24959
Tel: +972-4-987-3737; Fax: +972-4-987-3001
Email: qa@plastmed.com

Trade Name: *EQUASHIELD*™ Luer Lock Connector Pair

Common name: Closed drug transfer system

Classification: **Name**: Intravascular administration set
Product Code: LHI
Regulation No: 880.5440
Class: II
Classification Panel: General hospital

Predicate Devices: Modified EQUASHIELD™ Luer Lock Connector Pair is substantially equivalent to the original EQUASHIELD™ system for the preparation and administration of parenteral drugs, cleared under Plastmed's 510(k) number K083152.

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Device Description:

The EQUASHIELD™ Luer Lock Connector Pair is a closed system for drug transfer. It utilizes some of the predicate device components to create a closed system during drug transfer. The EQUASHIELD™ Luer Lock Connector Pair consists of a connector to an infusion set (Female Luer Lock Connector) and a connector to an IV catheter (Male Luer Lock Connector).

The connector pair provides closed system protection during connection and disconnection of a fluid path, thereby prohibiting the escape of the hazardous drug and its harmful vapors into the environment by air-tight enclosing of air and all contaminants within the system.

Indication for Use Statement:

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

Technological characteristics and Substantial Equivalence:

The modified EQUASHIELD™ Luer Lock Connector Pair is substantially equivalent to the original EQUASHIELD™ System that was previously cleared under 510(k) number K083152.

Both new and predicate devices have the same indication for use, same functions, same components design, similar and biocompatible materials and same characteristics. Certain changes that differs the modified device from the original (predicate) device were fully addressed.

The modifications performed do not affect the device's intended use and do not alter the device's fundamental scientific technology.

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Modified device verification and validation tests showed that it is as safe and as effective as the predicate device.

Non clinical performance data:

Test results support all labeling claims and substantial equivalency.
The modified device was tested in accordance to Plastmed's legally marketed device specification. All testing results demonstrated satisfactory performances and met all acceptance criteria.

Conclusions:

The evaluation of Plastmed's modified Device's bench tests demonstrated that the device performs as intended and that it is as safe and as effective as the predicate device.
Therefore, we believe it is substantially equivalent to Plastmed's legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Ms. Elissa Burg
Quality Assurance and Regulatory Affairs Manager
Plastmed Limited
Building No. 7
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Tefen Industrial Park, 24959
ISRAEL

OCT 22 2009

Re: K091389
Trade/Device Name: EQUASHIELD™ Luer Lock Connector Pair
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: October 7, 2009
Received: October 13, 2009

Dear Ms. Burg:

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.

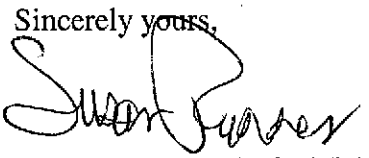
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

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Section 4 - Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091389

Device Name: EQUASHIELD ™ Luer Lock Connector Pair

Indications for Use:

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

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Division of General, Restorative and Neurological Devices

510(k) Number

Anthony D. Watson

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

510(k) Number: K091389