EQUASHIELD Medical Ltd.
Elissa Burg
Tel: +972 4 9873737
Fax: +972 4 9873001
elissa@equashield.com

Section 13 –510(K) SUMMARY

NOV 19 2010

510(K) SUMMARY
EQUASHIELD™ SYSTEM PROTECTIVE PLUG

Date of summary: October 31, 2010

510(k) Number K101940/S2

Applicant's Name: EQUASHIELD Medical Ltd.
Tefen Industrial Park
P.O.B 12, ISRAEL
Tel: (972)4-987-3737
Fax: (972)4-987-3001

Contact Person: Elissa Burg
Tefen Industrial Park
P.O.B 12, ISRAEL , 24959
Tel: +972-4-987-3737; Fax: +972-4-987-3001
Email: elissa@equashield.com

Trade Name: *EQUASHIELD*™ System Protective Plug

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: New EQUASHIELD™ System Protective Plug is substantially equivalent to the original EQUASHIELD™ System for the preparation and administration of parenteral drugs, cleared under 510(k) number K083152 and to the EQUASHIELD™ Luer Lock Connector Pair cleared under 510(k) number K091389.

EQUASHIELD Medical Ltd.
Elissa Burg
Tel: +972 4 9873737
Fax: +972 4 9873001
elissa@equashield.com

Device Description:

The EQUASHIELD™ System Protective Plug is used as a "cork" for blocking EQUASHIELD™ connector openings, thus providing the system with further protection, mainly during the transportation and conveying of the EQUASHIELD™ System together with other accompanied items (used routinely by the hospital), where EQUASHIELD™ components might be squeezed in a transportation container together with other items which could accidently cause damage due to penetration of such items into the EQUASHIELD™ System's connector ports.
The Protective Plug is inserted into the EQUASHIELD™ connector ports' openings and **mechanically** prohibits entrance of any accompanied items.

Indication for Use Statement:

The EQUASHIELD™ System 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.
The EQUASHIELD™ System has an additional Protective Plug accessory which functions as a feature that mechanically prohibits the entrance of any objects into the EQUASHIELD™ System by physically blocking and protecting the system's connector ports.

Technological characteristics and Substantial Equivalence:

The comparison table provided in our original submission's section 10 provides a detailed comparison between our new device and its predicates in order to support substantial equivalence.

The comparison table refers to:

Intended use; System components; Characteristics; Principles of operation; Technological characteristics; Sharps injury prevention feature; Target users; Intended environment of use; sterilization; materials and biocompatibility.

The table shows that in some features the Protective Plug is equivalent (due to the addition of the Protective Plug) to the predicates and in other features it is identical.

Elissa Burg
Tel: +972 4 9873737
Fax: +972 4 9873001
elissa@equashield.com

The new device differs from the predicates only in the fact that it is used as an additional accessory to the entire system and provides an additional benefit in protecting the system components' ports.

In all other features the new device is identical to the predicates as following described:

Both new and predicate devices are the same in terms of components design, materials, device characteristics, mechanical features, connections type, performances and technology features as the legally marketed EQUASHIELD™ System (K083152) and EQUASHIELD™ Luer Lock Connector Pair (K091389).

Therefore we have concluded that the EQUASHIELD™ System with Protective Plug accessory is substantially equivalent to the original EQUASHIELD™ System that was previously cleared under 510(k) number K083152 and the EQUASHIELD™ Luer Lock Connector Pair that was cleared under 510(k) number K091389.
The evaluation and tests results of the differences raised, showed that the new EQUASHIELD™ Protective Plug accessory is as safe and as effective as the predicate devices.

Non clinical performance data:

A conveyance simulation was performed by exposing the new device to the actual use conditions. Then, it was tested with accordance to the specification requirements in order to verify that the EQUASHIELD™ Protective Plug device performs as intended and without compromising the safe use of the entire EQUASHIELD™ system (K083152) and EQUASHIELD™ Luer Lock Connector Pair (K091389) which were used as predicate devices.
The tests that were conducted included: Visual tests; detachment tests; fluid flow through the entire system.
All functional tests results, post mimicking the actual conditions, met the specification predetermined acceptance criteria and demonstrated that the EQUASHIELD™ System components functioned appropriately after Protective Plug assembly and detachment and that it prevented the penetration of accompanying parts into EQUASHIELD™ ports during conveying.
We therefore believe that the tests results support all our labeling claims, substantial equivalency requirements and device's intended use.

EQUASHIELD Medical Ltd.
Elissa Burg
Tel: +972 4 9873737
Fax: +972 4 9873001
elissa@equashield.com

Conclusions:

The evaluation of EQUASHIELD Medical's new device's performance tests demonstrated that the device performs as intended and that it is as safe and as effective as the predicate devices.
In the light of the above, we believe it is substantially equivalent to EQUASHIELD Medical's legally marketed devices; EQUASHIELD™ System (K083152) and the EQUASHIELD™ Luer Lock Connector Pair (K091389) and appropriate for its intended use.

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

Ms. Elissa Burg
Quality Assurance and Regulatory Affairs Manager
Equashield Medical Limited
Tefen Industrial Park
P.O. B. 12, Israel, 24959

NOV 19 2010

Re: K101940
Trade/Device Name: EQUASHIELD™ System with Protective Plug
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: November 3, 2010
Received: November 5, 2010

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. 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.

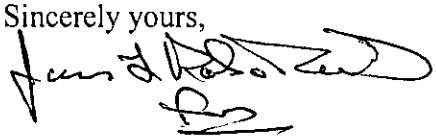
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

EQUASHIELD Medical Ltd.
Elissa Burg
Tel: +972 4 9873737
Fax: +972 4 9873001
elissa@equashield.com

Appendix D - Indications for Use Statement

INDICATIONS FOR USE STATEMENT

NOV 19 2010

510(k) Number (if known): K101940

Device Name: EQUASHIELD ™ System with Protective Plug

Indications for Use:

The EQUASHIELD™ System 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.

The EQUASHIELD™ System has an additional Protective Plug accessory which functions as a feature that mechanically prohibits the entrance of any objects into the EQUASHIELD™ System by physically blocking and protecting the system's connector ports.

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

11/19/10

510(k) Number

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

510(k) Number: K101940