September 21, 2018

Teva Medical Ltd., Migada Plant
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consulting
Piazza Albania 10
Rome, 00153
ITALY

Re: K180489
Trade/Device Name: TEVADAPTOR® Closed Drug Reconstitution and Transfer System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: ONB
Dated: August 14, 2018
Received: August 16, 2018

Dear Roger Gray:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180489

Device Name
TEVADAPTOR Closed Drug Reconstitution and Transfer System

Indications for Use *(Describe)*
TEVADAPTOR is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of the drug in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary in accordance with 21 CFR 807.92(c)
(K180489)

Device Name:	TEVADAPTOR® Closed Drug Reconstitution and Transfer System
Type of 510(k) submission:	Traditional
Date of Submission:	10 September 2018
Manufacturer:	Teva Medical Ltd., MIGADA Plant, North Industrial Zone Kiryat Shmona, 10258 ISRAEL
FDA Registration Number:	9611423
Owner/Operator Number:	9001925
510(k) Owner & Submitter:	Teva Medical Ltd., MIGADA Plant North Industrial Zone Kiryat Shmona, 10258 ISRAEL
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510(k) Application Correspondent:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10, 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	ONB
FDA Regulation Number:	880.5440
FDA Regulation Name:	Intravascular administration set
Classification Panel:	General Hospital
Common Name:	Closed Drug Reconstitution and Transfer System
FDA Classification:	Class II
FDA Identification:	Reconstitute and transfer antineoplastic and other hazardous drugs in healthcare setting indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare setting.

Indications for Use: TEVADAPTOR® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of the drug in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

Device Description:
The TEVADAPTOR® Closed Drug Reconstitution and Transfer System is a system of components that allows the safe reconstitution of liquid or pre-dissolved powder drugs into infusion bags, flexible bottles or syringes. Single, partial or multiple vials can be used for each infusion solution container. The TEVADAPTOR® Closed Drug Reconstitution and Transfer System prevents contamination of the user or

the environment by the drug through the use of elastomeric seals and an active carbon filter. Sterility of the drug in the vial is maintained because any air entering the vial during pressure equalization enters through of a hydrophobic acrylic copolymer membrane with a pore size of 0.2 micron.

The components of the previously cleared TEVADAPTOR® system are:

- Vial Adaptor 20 mm with 13 mm Vial Converter
- Vial Adaptor 28 mm
- Syringe Adaptor
- Spike Port Adaptor
- Connecting Set
- Luer Lock Adaptor
- Syringe Adaptor Lock

Each of the above component parts is available separately.

The purpose of this 510(k) is to add an additional component to the TEVADAPTOR® system already cleared for sale in the US, the description of which is:

- New component: TEVADAPTOR® Catheter Adaptor

The Catheter Adaptor provides closed system protection during connection and disconnection of the fluid path between the Syringe Adaptor of the TEVADAPTOR® system and a bladder catheter (not supplied), while allowing safe administration of cytotoxic drugs to the bladder.

The Catheter Adaptor connects to the TEVADAPTOR® Syringe Adaptor, the short length of polymeric tubing of the adaptor is connected to the adaptor main body, which in turn is connected to the universal bladder catheter connector. A vented cap is supplied over the universal connector. The universal bladder catheter connector connects to a bladder catheter (not supplied).

Device performance:
Performance tests have been conducted on both non-aged sample devices and samples that have been aged for 12 months following routine sterilization.

These tests included:

- Air leakage test – to demonstrate that there is no leakage between the connections of the Catheter Adaptor components under an air pressure of 0.7 bar for at least 15 min. No failures observed at T0 and T12mo.
- Catheter Adaptor component disconnection force test – to demonstrate that the disconnection force between the component connections shall not be less than 3.00 kgf at a speed of 500 mm/min and shall have a gluing depth of 8.0 mm. No failures observed at T0 and T12mo.
- Catheter Adaptor component unclogged device test – to demonstrate that air bubbles appear in the water bath for at least 15 min. No failures observed at T0 and T12mo.
- Non-Luer universal connector to a bladder catheter - to demonstrate that the connection between the non-Luer universal connector of the Catheter Adaptor and the bladder catheter is sealed to prevent user exposure to hazardous drugs. Testing was carried out in accordance with ISO 8536-4:2010, section 6.11.
- Chemical resistance test - to demonstrate that the device is compatible with cytotoxic drugs.

The packaging materials and process for the Catheter Adaptor, together with sterilization method and parameters, are unchanged from those utilized for the TEVADAPTOR® Connecting Set component cleared under K141448.

The subject devices are supplied sterile, with an SAL of 10^{-6}. The devices are sterilized by ethylene oxide, with the same parameters as the remainder of the TEVADAPTOR® components, as described in K141448 for the predicate device.

In addition, biocompatibility tests have been carried out on the components of the Catheter Adaptor to demonstrate that the three new materials used meet the requirements of ISO 10993 and FDA guidance.

Comparison with predicate device:
The predicate device selected for comparison with the revised TEVADAPTOR® Closed Drug Reconstitution and Transfer System is:

Predicate Device: ..... TEVADAPTOR® Closed Drug Reconstitution and Transfer System
510(k) Sponsor: ..... Teva Medical
510(k) Number:..... K141448
Clearance Date:..... 23 January 2015
FDA Product Code:..... ONB
Regulation Name: ..... Intravascular Administration Set
Regulation No: 880.5440

The only difference between the predicate and subject device is the addition of a further TEVADAPTOR® System component, this being the Catheter Adaptor. Specific bench tests have been successfully completed to ensure the Catheter Adaptor connects effectively, without leakage, to the other relevant TEVADAPTOR® components, and to a range of commercially available bladder catheters.

Three new materials are introduced to the TEVADAPTOR® System by the inclusion of the Catheter Adaptor. These materials have been subjected to biocompatibility tests in accordance with the applicable parts of ISO 10993 and FDA guidance for the nature of patient contact and duration of contact, and to tests to demonstrate compatibility with an aggressive solvent commonly used with cytotoxic drugs for bladder treatment.

The Indications for Use statement for the TEVADAPTOR® System with the Catheter Adaptor is unchanged from the predicate, K141448.

A reference device is included within this submision, to provide support for inclusion of a bladder catheter within a submission for a Closed Drug Reconstitution and Transfer System. This reference device is the 'Equashield Closed System drug Transfer Device (CSTD)', cleared by FDA on July 3, 2017, under 510(k) K170706, which includes the 'Catheter Luer Lock Adaptor (LL-1C)' component.

Substantial Equivalence Conclusion:
Based on the performance testing conducted on the Catheter Adaptor, the addition of the Catheter Adaptor to the TEVADAPTOR® System does not raise new types of safety and effectiveness questions. It is concluded that the TEVADAPTOR® System modified by the introduction of the Catheter Adaptor is substantially equivalent to the identified predicate device cleared under K141448, which is already in interstate commerce within the USA.