**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 16, 2017

Teva Medical Ltd., Mitgada Plant
c/o Mr. Roger Gray
Donawa Lifescience Consulting
Piazza Albania 10
Rome 00153
ITALY

Re: K170680
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: April 12, 2017
Received: April 17, 2017

Dear Mr. 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. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,


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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K170680

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**K170680**

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

| | |
|---|---|
| **Device Name:** | TEVADAPTOR® Closed Drug Reconstitution and Transfer System |
| **Type of 510(k) submission:** | Special |
| **Date of Submission:** | May 12, 2017 |
| **Manufacturer:** | Teva Medical Ltd., MIGADA Plant<br>North Industrial Zone<br>Kiryat Shmona 10258<br>ISRAEL |
| **FDA Registration Number:** | 9611423 |
| **Owner/Operator Number:** | 9001925 |
| **510(k) Owner & Submitter:** | Teva Medical Ltd., MIGADA Plant<br>North Industrial Zone<br>Kiryat Shmona 10258<br>ISRAEL |
| **Phone:**<br>**Fax:** | +972-4-6908826<br>+972-9-892-1659 |
| **510(k) Application Correspondent:** | Mr Roger Gray<br>VP Quality and Regulatory<br>Donawa Lifescience Consulting<br>Piazza Albania 10<br>00153 Rome<br>Italy<br><br>Phone: +39 06 578 2665<br>Fax: +30 06 574 3786<br>Email: rgray@donawa.com |
| **FDA Product Code:** | ONB |
| **FDA Regulation Number:** | 880.5440 |
| **FDA Regulation Name:** | Set, Administration, Intravascular |
| **Classification Panel:** | General Hospital |
| **Common Name:** | Closed Drug Reconstitution and Transfer System |
| **FDA Classification:** | Class II |

**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.

**Predicate Device:**

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

| | |
|---|---|
| Predicate Device Name: | 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 Number: | 880.5440 |

**Reference Device:**

| | |
|---|---|
| Reference Device Name: | TEVADAPTOR® Closed Drug Reconstitution and Transfer System |
| 510(k) Sponsor: | Teva Medical |
| 510(k) Number: | K071741 |
| Clearance Date: | 24 September 2007 |
| FDA Product Code: | LHI |
| Regulation Name: | Intravascular administration set |
| Regulation Number: | 880.5440 |

**Device Description:**

The TEVADAPTOR® Closed Drug Reconstitution and Transfer System is a system of components that allows the 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 purpose of this Special 510(k) is to add an additional design of one of the components, the TEVADAPTOR® Syringe Adaptor Lock.

The Syringe Adaptor (SA) Lock is one component of the system which is intended for connection to a standard Luer lock syringe. A non-latex elastomer protector covers the liquid dispensing needle tip. A clamp mechanism reversibly connects the Syringe Adaptor Lock to the other components of the TEVADAPTOR® system. The TEVADAPTOR® Syringe Adaptor Lock includes a stainless steel needle that is shielded at all times during preparation, use and disposal. The Syringe Adaptor Lock is supplied with a cap.

Disconnection of a syringe is not possible with the Syringe Adaptor Lock, because of a design change from the syringe adaptor that introduces a two-component distal hub. One of these components attaches, and rotates within the second component, together with the syringe, if disconnection is attempted.

The components of the TEVADAPTOR® system available separately are:

- Vial Adaptor 20 mm with 13 mm Vial Converter
- Vial Adaptor 28 mm

- Syringe Adaptor
- Syringe Adaptor Lock
- Spike Port Adaptor
- Connecting Set
- Luer Lock Adaptor

The environment of use is unchanged from that of the predicate TEVADAPTOR® system cleared under K141448.

**Device Performance Testing:**

Bench testing has been carried out on the Syringe Adaptor Lock to demonstrate equivalence with the Syringe Adaptor, including:

- Bidirectional flow
- Needle to Syringe Adapter Luer-lock disconnection test
- Breakage of SA Lock Luer retention teeth
- Disconnection of male luer and SA Lock
- Luer fitting compliance with ISO 594/1 & 2, including:
    - Gauging test
    - Resistance for overriding
    - Unscrewing torque
    - Ease of assembly
    - Liquid leakage
    - Air leakage
    - Separation force of conical fitting assembly
    - Stress cracking
- Visual inspection for absence of cracks

The packaging materials and process for the Syringe Adaptor Lock are unchanged from those utilized for the Syringe Adaptor and other TEVADAPTOR® components 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.

No additional biocompatibility tests have been carried out on the components of the Syringe Adaptor Lock, because all materials within the fluid path of the item are unchanged from the Syringe Adaptor cleared under K141448 or its previous design, cleared under K071741, included within this submission as a reference device. The material of the hub component of the syringe adaptor lock is identical to the material of the hub component of the syringe adaptor cleared under K071741.

A risk assessment of the changes in design introduced by the Syringe Adaptor Lock concluded that any new risks identified were adequately mitigated and verified by means of bench testing.

**Comparison with Predicate Device:**

The major difference between the Syringe Adaptor and Syringe Adaptor Lock is in the 'Luer Hub' component, which has been replaced by two components, the 'SA Luer-lock' and the 'SA Hub-lock'. The SA Hub-lock and End Cap for the Syringe Adaptor Lock have new colorants which are not used in the Syringe Adaptor components, for easy user-recognition purposes, however neither of these new components of the Syringe Adaptor Lock are in the fluid path, being external only components.

The separation of the 'Luer Hub' into two components has allowed the design to permanently attach a Luer syringe to the Syringe Adaptor Lock, whereas a Luer syringe can be disconnected from the predicate Syringe Adaptor. When attaching a Syringe to the Syringe Adaptor Lock, the SA Luer-lock will rotate with the Syringe until two teeth on the SA Luer-lock component engage with two of the four cam upstands on the inner circumference of the SA Hub-lock component. Once the SA Luer-lock teeth have engaged with the SA Hub-lock, no further rotation of the SA Luer-lock is possible.

If disconnection of the Syringe from Syringe Adaptor Lock is attempted, the SA Luer-lock will rotate with the Syringe. When a quarter rotation is reached, by means of a cam action, the SA Luer-lock teeth will slip over the upstands on the SA Hub-lock inner surface, and will thus continue to rotate with the Syringe, preventing disconnection of the Syringe from the Syringe Adaptor Lock.

The only other difference is that 'Main Body' component of the Syringe Adaptor has been shortened by 5.2 mm to accommodate the above new components within the Syringe Adaptor Lock.

All other components of the TEVADAPTOR® system remain unchanged from those cleared under K141448.

**Substantial Equivalence Conclusion:**

Based on the performance testing conducted on the subject device, the Syringe Adaptor Lock, does not raise new types of safety and effectiveness questions. It is concluded that the TEVADAPTOR® device that has been modified by the introduction of the Syringe Adaptor Lock is substantially equivalent to the identified predicate device cleared under K141448, which is already in interstate commerce within the USA.