TEVADAPTOR®

Keeps you safe in a click

Tevadaptor® is FDA cleared under ONB product code

The Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices and others.

Tevadaptor® is a leading closed system transfer device (CSTD) for antineoplastic and hazardous drug reconstitution and transfer, designed to meet the highest safety standards.

Tevadaptor® has been protecting pharmacists, nurses and patients alike since 2005. The OnGuard® brand is marketed in the USA, and altogether the device is distributed in over 25 countries worldwide.

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What does ONB clearance mean?

It means that the FDA has found that Tevadaptor® meets the standard for closed system transfer devices.

What is unique about Tevadaptor® compared to other ONB devices?

Tevadaptor® has the patented TOXI-GUARD® system, which prevents airborne contaminants from entering the drug vial as well as the escape of hazardous drug vapors, aerosols or droplets to the environment.

The TOXI-GUARD® patent enables rapid equalization of pressure within the drug vial as diluent is added or drug is withdrawn and retains sterility of the drug vials even after first use.

What is the significance of the FDA ONB Product Code?

Prior to establishment of the ONB product code, Closed System Drug Transfer Devices such as Tevadaptor® were evaluated by the FDA under the General Hospital Devices Branch (GHDB).
The ONB product code established a new standard for the industry that is specific for Closed System Drug Transfer Devices.

The ONB code is a part of the regulation description for Intravascular Administration sets, but it is specific for CSTDs.
ONB clearance is attained following presentation of data and tests that verify the device prevents exit of fluids, droplets or aerosoles and in parallel prevents entry of microbial contaminants.

How does the FDA define the ONB Product Code?[1]

In 2012, the U.S. Food and Drug Administration (FDA) began issuing 510(k) clearances under a new product code "ONB code" that was specific to CSTDs. All CSTDs that are FDA cleared under the ONB code are considered as CSTDs regardless of their technology (physical barrier or air-cleaning).

Device
Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

Regulation Description
Intravascular Administration Set

Definition
Reconstitute and transfer antineoplastic and other hazardous drugs in healthcare setting indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare setting

Physical State
According to the FDA definition, the device should include multiple parts to enable a closed connection starting from the vial, through the syringe and ending in an IV set or transfer bag. It states that the Vial Adaptor should have piercing spikes and a Luer-Lock connector fitted with an elastomeric membrane for a sealed connection. A needle-free access port and a side-pressure equalizing protector unit are optional.

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.

1. FDA site: https://www.fda.gov/default.htm