



Section II - 510(k) Summary of Safety and Effectiveness

Submitter:

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Device Name:

- Trade Name - None
- Common Name - Disposable Transfer Needle
- Classification Name - Intravascular Administration Set (I.V. Fluid Transfer Set), per 21 CFR § 880.5440.

Devices for Which Substantial Equivalence is Claimed:

- Baxter Healthcare Corporation, Hyland Division's Transfer Device
- Venusa, Ltd.'s Transfer Device TR8

Device Description:

The device is a disposable transfer needle which is used for transferring an intravenous diluent solution from one container to another which results in the reconstitution of lyophilized product. One end of the device is inserted through the stopper of the diluent vial while the other end of the transfer device is inserted through the stopper of the lyophilized product. The diluent vial is inverted above the lyophilized product and the vacuum within the product vial draws in the diluent to achieve reconstitution.

Intended Use of the Device:

The intended use of the disposable transfer needle is for transferring an intravenous diluent solution from one container to another which results in the reconstitution of lyophilized product.

Substantial Equivalence:

The disposable transfer needle is substantially equivalent to several other legally marketed devices in the United States. The transfer devices marketed by Baxter Healthcare Corporation, Hyland Division and Venusa, Ltd. function in a manner identical to and is intended for the same use as the product manufactured by _____