K961495

510(k) SUMMARY
Huber Needle Extension Sets

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Submitted by:

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Proposed Device:
Huber Needle Extension Sets

Predicate Devices:
Micro-Med, Inc. Core Resistant Huber Needle Infusion Set
Baxter Solution Administration Sets with InterLink® Injection Site
Baxter InterLink® T-Connector Extension Sets

Proposed Device Description:

The proposed products consist of a line of Huber Needle Extension Sets which may be manufactured in four basic types:

Huber Needle Extension Set without an injection site
Huber Needle Extension Set with a standard injection site
Huber Needle Extension Set with an InterLink® Y-injection site (Y-Site)
Huber Needle Extension Set with an InterLink® T-injection site (T-Site)

Statement of Intended Use:

Baxter's proposed Huber Needle Extension Sets have the same intended use as the Micro-Med, Inc. Core Resistant Huber Infusion Sets covered by K950597. They are intended for the administration of solutions and drugs into vascular implant ports. The proposed Huber Needle Extension Sets with InterLink® Y-Site or InterLink® T-Site, like other products containing the InterLink® injection site are designed to reduce the risk of accidental needle sticks when used in conjunction with the InterLink® cannula, as part of a "needleless" IV access system.

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Summary of Technological Characteristics of New Device to Predicate Devices

The proposed sets will be manufactured for Baxter by Micro-Med, Inc. and are similar to Micro-Med, Inc. Huber Needle Infusion Sets cleared under K950597. Like the Micro-Med, Inc. sets, the proposed sets will be used to administer drugs and solutions through vascular implant ports. The same Huber needle and winged body needle securement component which is used in the Micro-Med, Inc. sets to access implantable ports will be used in the proposed sets. Like the Micro-Med, Inc. sets, the proposed Huber Needle Extension Sets will vary in needle gauge, needle length, tubing diameter and set length.

The proposed sets will also incorporate components which are used in currently marketed Baxter solution administration sets. For example, the same InterLink® pre-slit injection site used in other Baxter InterLink® sets and covered by K925126 and K883638 will be incorporated into the proposed set line. The InterLink® injection site is designed to reduce the risk of accidental needle sticks when used with the InterLink® cannula.

All solution contacting components for the proposed sets are used in Micro-Med, Inc. Huber Infusion Sets or in other marketed Baxter solution administration sets. Therefore, the proposed set line results from a combination of previously cleared components and set configurations. The main differences include adaptation of the T-connector component for an in-line tubing connection and use of a cyanoacrylate adhesive to bond the outside of the set tubing to the needle wing body. The adhesive is applied to the bond area such that there is no contact with the solution path of the set.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

Data regarding the functional performance of the proposed sets has been generated. Testing included flow rate, total volume, pressure testing of set bonds and tensile strength testing. Performance testing indicates that the proposed sets meet or exceed all functional requirements and support their suitability for use.