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510(k) SUMMARY

InterLink® Micro-Infusion Manifold Extension Sets

Submitted by:

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Proposed Device:

InterLink® Micro-Infusion Manifold Extension Sets

Predicate Devices:

InterLink® T-Connector Extension Set
PDI Manifold Extension Sets

Proposed Device Description:

The proposed InterLink® Micro-Infusion Manifold will be combined with various configurations of extension sets for the administration of IV solutions. The manifold incorporates three InterLink® injection sites mounted to a central barrel or solution conduit. The manifold provides multiple InterLink® access sites for bolus injection or infusion of parenteral solutions into the intravenous line. The integrated design of the manifold facilitates administration of multiple infusions with minimal fluid residual volume. Use of the InterLink® Micro-Infusion Manifold and InterLink® cannula will reduce the risk of accidental needle sticks when accessing the IV line.

There is one material in the proposed manifold which is a material new to Baxter devices. A cyanoacrylate adhesive may be used to bond the checkvalve to the manifold housing and the manifold luer to the extension set tubing. The other materials in the proposed InterLink® Micro-Infusion Manifold and the extension sets incorporating it have been previously tested and used in other marketed devices for similar IV solution administration applications.

Statement of Intended Use:

Extension Sets with the InterLink® Micro-Infusion Manifold are intended for use with a vascular access device for blood sampling and the administration of multiple drugs and solutions. These devices, like others containing the InterLink® injection site, are

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designed to reduce the risk of accidental needle sticks when used with the InterLink® cannula, as part of a “needleless” IV access system.

Summary of Technological Characteristics of New Device to Predicate Devices

Extension sets with the proposed InterLink® Micro-Infusion Manifold are similar to Baxter’s InterLink® T-Connector Extension Set previously found substantially equivalent under K921899. Both products incorporate the InterLink® injection site septum into the top of the manifold or T-connector in an integrated design which allows needleless access with minimal residual volume.

Extension Sets with the proposed InterLink® Micro-Infusion Manifold are also similar to the Manifold Extension Sets, manufactured by PDI Medical Products. Both Baxter and PDI manifolds consist of a one-piece integrated design with multiple access sites.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

The biological and chemical reactivity of the new adhesive material has been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The material was found to be acceptable for its intended use.

Data regarding the functional performance of the proposed manifold have been generated. A description of the functional testing along with test results is provided. The data indicate that the proposed manifold meets or exceeds all functional requirements and support its suitability for use.