K964850

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510(k) SUMMARY

Solution Administration Sets with 0.22 Micron Filter

Submitted by:

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Proposed Device:
0.22 Micron Filter Sets

Predicate Devices:
Abbott Solution Sets with 0.22 Micron Filter
Baxter Solution Sets with 0.22 Micron Filter

Proposed Device Description:

The subject of this submission is the Millipore 0.22 micron filter which Baxter intends to incorporate into various configurations of solution sets for the administration of intravenous solutions. The filter is manufactured by Millipore and has been recently cleared for marketing in Abbott solution administration sets covered by K960466.

Baxter will purchase the 0.22 micron filter from Millipore and incorporate it into currently marketed solution administration sets. Baxter is making no changes to the design, components or materials of the Millipore filter.

Summary of Technological Characteristics of New Device to Predicate Devices

The Millipore 0.22 micron filter to be incorporated in Baxter solution administration sets is identical to that which has been recently cleared for marketing in Abbott solution administration sets under K960466 for the same intended use. Baxter is making no changes to the design, components, or materials of the Millipore filter. The proposed Baxter sets are identical to currently marketed Baxter sets except for the change in the 0.22 micron filter to the Millipore I.V. Express™ filter. All other components of the solution administration sets remain unchanged.

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Discussion of NonClinical Tests

Data regarding the functional performance of the 0.22 micron filter were generated by Millipore. Testing included Reverse Pressure Filter Integrity, Unit Venting, Gravity Flow, Inlet Axial Stress, Housing Integrity/Female Luer Fitment, Forward Pressure Filter Integrity, Downstream Particle Count, Accelerated Endurance, Outlet Deflection Stress, In-Line Filter Wettability, Bacterial Endotoxins, Bioburden Evaluation, Burst Strength, and MVI Resistance. The data indicate that the filter meets or exceeds all functional requirements.

Conclusions Drawn from Nonclinical Tests

Functional, microbiological, and drug compatibility data indicate that the proposed filter meets or exceeds all functional requirements and support its suitability for use in Baxter sets.