510(k) SUMMARY

K964853

Submitted by:

Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

MAR 3 1 1997

Date Prepared:
November 26, 1996

Proposed Device:
IntraVia™ Empty Plastic Container

Predicate Devices:
Viaflex® Empty Plastic Container

Proposed Device Description:

Baxter is currently marketing a line of empty Viaflex® plastic containers used for the preparation and administration of drug admixtures. We propose to change the materials of the container sheeting, administration and medication ports and medication site and market the container under the tradename IntraVia™ Container, Empty.

The primary reason for the change in container materials is to allow a change in sterilization methods from ETO to gamma sterilization. In addition, use of the IntraVia™ container in place of the Viaflex® container offers several benefits including use of standard thermoplastic methods for recycling and reduction in the amounts of environmental contaminants released during incineration of PVC such as hydrochloric acid and dioxins. The material change in the medication site is being made to improve user safety by eliminating the potential for sensitivity reactions associated with natural rubber proteins.

Summary of Technological Characteristics of New Device to Predicate Devices

The proposed IntraVia™ container is the same in overall design and intended use as the currently marketed Viaflex® container. The IntraVia™ container differs from the Viaflex® container in material composition and sterilization method.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

The biological and chemical reactivity of the new container materials have been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The materials were found to be acceptable for their intended use.

Data regarding the functional performance of the proposed empty IV container and its drug compatibility characteristics have been generated. Functional performance studies included residual volume, fill volume, spike insertion/removal force and burst testing. Performance testing indicate that the proposed container meets or exceeds all functional requirements and support its suitability for use.

Drug compatibility studies were conducted with commonly admixed drugs or those that have a high potential to adsorb to the container under representative storage conditions. Results of drug compatibility evaluations support the suitability of the new container for its intended use.