

K962696

II 510(k) Summary of Safety and Effectiveness
in Accordance with SMDA'90

APR -3 1997

B. Braun Medical, Inc July 9, 1996
824 Twelfth Avenue
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CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Perifix Pediatric Epidural Kit

TRADE NAME: Conduction Anesthesia Kit

CLASSIFICATION NAME:

Anesthesiology
Class II, 73 CAZ, Conduction Anesthesia Kit
21 CFR 868.5140

SUBSTANTIAL EQUIVALENCE¹ TO:

510(k) number	Name	Applicant
K813186	Perifix Set for Epidural Anesthesia	Burrton Medical
K893766	Lifecare Epidural Catheter	Abbott
K953467	Spinal Anesthesia Tray	Becton Dickinson

DEVICE DESCRIPTION:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce the Perifix Pediatric Epidural Kit. The Perifix Pediatric Epidural Kit is designed to provide pediatric patients, who are undergoing a surgical procedure, with regional anesthesia below the level of the tenth thoracic vertebrae.

¹ The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

MATERIAL:

The Perifix Pediatric Epidural Kit is composed of materials that have been tested in accordance with Tripartite Guidance for Plastics and determined to be suitable for the intended use of this product.

SUBSTANTIAL EQUIVALENCE:

The Perifix Pediatric Epidural Kit is equivalent in materials, form, and intended use to the Perifix Set for Epidural Anesthesia with Tuohy Needle and Catheter K813186 currently marketed by B. Braum Medical (formerly Burrton Medical. It is also equivalent to Abbott's Epidural Catheter K893766 and Becton Dickinson's K953467 Spinal Anesthesia Tray. There are no new issues of safety or effectiveness raised by the Perifix Pediatric Epidural Kit.

SAFETY AND EFFECTIVENESS:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.