APR -7 1997

K970287

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

B. Braun Medical, Inc
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PRODUCT NAME: Lumbar Puncture Kit

TRADE NAME: Lumbar Puncture Kit

CLASSIFICATION NAME: General Hospital
Class II, 80 FMJ, Spinal Fluid Manometer
21 CFR 880.2500

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K932569	Pencil Point Spinal Needle and Tray	B. Braun of America
K920305	Pharmaseal Clear Hub Spinal Needle	Baxter Healthcare Corporation

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 Lumbar Puncture Kit. The Lumbar Puncture Kit is designed to collect samples of cerebralspinal fluid (CSF) from a patient while undergoing a lumbar puncture procedure. This device is also designed to attach a manometer to measure intracranial pressure (ICP), detect blood in CSF, inject dyes and gasses into the spine for radiologic studies, and to administer drugs or anesthesia between the third and fourth lumbar vertebrae in adult or pediatric patients.

[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 Lumbar Puncture Kit contains components that have already been reviewed and cleared by the FDA for their intended use.

SUBSTANTIAL EQUIVALENCE:

The Lumbar Puncture Kit is equivalent in components and intended use to the Pencil Point Spinal Tray currently marketed by B. Braun Medical (formerly B. Braun of America). It is also equivalent to the Lumbar Puncture Kit manufactured by Baxter. There are no new issues of safety or effectiveness raised by the Lumbar Puncture 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.