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

B. Braun Medical, Inc
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CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Closed Fluid Collection System

TRADE NAME: Fluid Delivery Tubing

CLASSIFICATION NAME:

General Hospital
Class II, 80 FPK, Fluid Delivery Tubing
21 CFR 880.5440

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
	Collection Protection Station	NAMIC
	Disposal Depot	Merit Medical

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 Closed Fluid Collection System. The Closed Fluid Collection System is used for acute and longterm abscess drainage, pleura drainage, and chest drainage.

[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 Closed Fluid Collection System 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 Closed Fluid Collection System is equivalent in materials, form, and intended use to Closed Fluid Collection Systems currently marketed by Merit Medical and NAMIC. There are no new issues of safety or effectiveness raised by the Closed Fluid Collection System.

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.