

K954123

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

B. Braun Medical, Inc
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PRODUCT NAME: Low Profile SafSite® Y-Site
TRADE NAME: Filtered Extension Sets

CLASSIFICATION NAME:

General Hospital
Class II, 80 FPA, Intravascular Administration Set
21 CFR 880.5860

SUBSTANTIAL EQUIVALENCE TO:

510(k) number	Name	Applicant
K942988	Filtered Extensions Sets	B. Braun of America

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 Low Profile SafSite® Y-Site. The component is used to provide needle-free access in I.V. and Extension Sets.

MATERIAL:

The low Profile SafSite® Y-Site is composed of materials that have been tested in accordance with Tripartite Guidance for Elastics and determined to be suitable for the intended use of this product.

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.

SUBSTANTIAL EQUIVALENCE :

The Low Profile SafSite® Y-Site is equivalent in materials, form, and intended use to Filtered Extension Sets currently marketed by B. Braun of America. There are no new issues of safety or effectiveness raised by the Low Profile SafSite® Y-Site.

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.