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

K955585

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PRODUCT NAME: V2 Injection Site

TRADE NAME: Intravascular Administration Set

CLASSIFICATION NAME:

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

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K942988	Filtered Extension 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 the V2 Injection Site. The V2 Injection Site is designed to provide needle-free access on I.V. and Extension Sets as an alternative to latex injection sites or other needle-free access systems. It may be accessed with standard male luer connectors and requires no special accessory devices.

[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 V2 Injection Site 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 V2 Injection 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 V2 Injection 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.