

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

K902377

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

**Product Name:** Volume Control Delivery Syringe

**Trade Name:** Angiographic Injector Syringe

**Classification name:**

Cardiovascular  
 Class II, 74DXT  
 21 CFR 870.1650

**SUBSTANTIAL EQUIVALENCE<sup>1</sup> TO:**

Name	510(k) number	Applicant
Angiographic Injector Syringe	K902377	Angeion

**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 a Volume Control Delivery Syringe. The Volume Control Delivery Syringe is used for the controlled inflation of balloon catheters during angioplasty procedures.

<sup>1</sup> 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 Volume Control Delivery Syringe is composed of materials that have been tested in accordance with the ISO Standard 10993 and have been determined to be suitable for the intended use of this product.

**Substantial equivalence:**

The Volume Control Delivery Syringe is similar in materials, form, and intended use to the Angiographic Injector Syringe cleared by Angeion and marketed by B. Braun Medical Cardiovascular Division. There are no new issues of safety or effectiveness raised by the Volume Control Delivery Syringe.

**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.