

K964352

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

JAN 28 1997

October 28, 1996

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

Product Name: TORQUE DEVICE

Trade Name: LTD Torque Device

Classification name: Catheter Guide Wire

Cardiovascular
Class II, 74DQX
21 CFR 870.1330

SUBSTANTIAL EQUIVALENCE¹ TO:

| 510(k) number | Name | Applicant |
|---------------|---------------------|---------------|
| K903606 | Torque Device | Namic |
| K936032 | Scout Torque Device | 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 a Torque Device. The guidewire torque device is a cylindrical clamp which slides over the proximal end of a guidewire. The device is used to facilitate the manipulation of a guidewire into a vein or artery.

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 Torque Device 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 Torque Device is similar in materials, form, and intended use to the Torque Device cleared by Namic and the Scout Torque Device cleared by Merit Medical. There are no new issues of safety or effectiveness raised by the Torque Device.

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.