

FEB 10 1997

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

K962084

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

PRODUCT NAME: Omnican Syringe
TRADE NAME: Piston Syringe

CLASSIFICATION NAME:

General Hospital
Class II, 80 FMF
21 CFR 880.5860

SUBSTANTIAL EQUIVALENCE¹ TO:

510(k) number	Name	Applicant
K941657	Insulin Syringe	Becton Dickinson

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 Omnican Syringe. The Omnican Syringe is designed to be used for subcutaneous, injection. The syringes are packaged in boxes of 100 each. Each box contains a magnifier to assist in reading the scale on the syringe barrel. The following is a list of article numbers that we intend to market after the clearance of this device:

Article Number	Name	Description
09151150	Omnican 100	1 ml for insulin 100 I.U./1 ml, integral needle
09151168	Omnican 50	0.5 ml for insulin 100 I.U./1 ml, integral needle
09151176	Omnican 30	0.3 ml for insulin 100

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 Omnican Syringe is composed of materials that have been tested in accordance with ISO 10993 for plastics and determined to be suitable for the intended use of this product.

SUBSTANTIAL EQUIVALENCE:

The Omnican Syringe is identical in materials, form, and intended use to the Insulin Syringe currently marketed by Becton Dickinson. There are no new issues of safety or effectiveness raised by Omnican 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.