

APR 30 1996

K952631

II 510(k) Summary

B. Braun Medical, Inc
824 Twelfth Avenue
Bethlehem, PA 18018
(610)691-5400

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CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Hemodialysis Blood Circuits

TRADE NAME: Braun Hemodialysis Blood Circuits

CLASSIFICATION NAME:

Gastroenterology and Urology
Class II, 78 KOC, Hemodialysis Blood Circuits
21 CFR 876.5820

SUBSTANTIAL EQUIVALENCE¹ TO:

<u>510(k) number</u>	<u>Name</u>	<u>Applicant</u>
K884243	Blood Tubing Set	Mediflex International Inc.

DEVICE DESCRIPTION:

B. Braun Medical Inc. intends to introduce into interstate commerce the Braun Hemodialysis Blood Circuits in various configurations. The configurations can be summarized tubing segments intended for use in transporting blood from a patient's vascular access device to hemodialyzer systems. Also, the tubing segments intended for use in transporting blood to a patient's vascular access device from such a system. The various configurations account for user preferences and various hemodialysis systems currently marketed. These all have the similar design and performance characteristics.

¹ The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to be applicable to patent infringement suits or any other patent matter related to this product or the technology used to manufacture the product.

MATERIAL:

B. Braun Medical certifies that the biocompatibility tests recommended in the Tripartite Guidance for this category of contact duration will be completed for the materials use in the manufacture of the device.

SUBSTANTIAL EQUIVALENCE:

The Braun Hemodialysis Blood Circuits are equivalent in materials, form, and intended use to the Blood Tubing Set currently marketed by Mediflex International Inc. There are no new issues of safety or effectiveness raised by the Braun Hemodialysis Blood Circuits.

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; sterility, pyrogenicity (endotoxin/ LAL Method), 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 physical testing for the Braun Hemodialysis Blood Circuits are defined in detail in the "Device Master Records".

The Braun Hemodialysis Blood Circuits follow the recommended performance standards outlined by The Association for the Advancement of Medical Instrumentation in the draft standard AAMI RD17R-6/94.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.