

Fresenius Compodock
510(k) Premarket Notification

B 204007 C

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name: Fresenius Medical Care North America
Address: 95 Hayden Ave
Two Ledgesmont Center
Lexington, MA 02420
Phone: 1-781-402-9068
Fax: (781) 402-9635
Contact Person: Arthur Eilinsfeld, Director of Regulatory Affairs
Date of Preparation: 7 October 2004

B. Device Name:

Trade Name: Fresenius Compodock
Common/Usual Name: Sterile Tubing Welder
Classification Name: Not currently assigned

C. Predicate Device Name:

The predicate device for the Fresenius Compodock is the following:

- Terumo Sterile Tubing Welder SC-201A (TSCD) - #BK970008 (5/28/98).

D. Device Description/Indications for Use:

The intended use for the Fresenius Compodock is equivalent to that for the Terumo Sterile Tubing Welder and is as follows:

Intended Use

The Compodock is a high-frequency connection device that permits the sterile connection of two sterile, standard medical PVC tubing sets (such as those on blood bags, leukocyte depletion filters, and apheresis sets, for example).

000055

Summary of Safety and Effectiveness

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius Compodock is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES - The intended use for the Fresenius Compodock is equivalent to that for the Terumo Sterile Tubing Welder and is as follows:

Intended Use - Compodock

The Compodock is a high-frequency connection device that permits the sterile connection of two sterile, standard medical PVC tubing sets (such as those on blood bags, leukocyte depletion filters, and apheresis sets, for example).

Intended Use - Terumo Sterile Tubing Welder (#BK970008)

The Terumo TSCD (model SC-201A) is a system for automatically connecting in sterile manner two sections of tubing.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO - The features included in the Fresenius Compodock are equivalent to those present on the Terumo Sterile Tubing Welder and raise no new types of safety or effectiveness questions. Table III-1 provides a comparison of the features of the Compodock and Terumo Sterile Tubing Welder.

4. Does descriptive or performance information demonstrate equivalence?

YES - Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Compodock and demonstrates that it is substantially equivalent to other commercially available sterile tubing welders.

F. Safety Summary

The Fresenius Compodock has undergone rigorous software validation and performance testing, including electromagnetic compatibility testing, and extensive dock testing. The results of this testing indicate that the Fresenius Compodock is safe and effective for its intended use and performs as expected.

B2040076

Fresenius Compodock
510(k) Premarket Notification

Summary of Safety and Effectiveness

G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. This information promotes safe and effective use of the device.

000057