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

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

August 29, 1996

CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Dialog Dialysis Machine

TRADE NAME: Single Patient Dialysate Delivery System

CLASSIFICATION NAME:

Gastroenterology & Urology
Class II, 78 FKP, Single Patient Dialysate Delivery System
21 CFR 876.5820

SUBSTANTIAL EQUIVALENCE[1] TO:

510 (k) Number	Applicant	Description
K854367, K850569 Modified	Organon Teknika	HD Secura Dialysis Unit
K880459	CD Medical	480 High-Flow Ultrafiltration Control Dialysate

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 the Dialog Dialysis Machine. The Dialog Dialysis Machine is an artificial kidney system used for the treatment of patients with renal failure or toxic conditions. The device consists of an extracorporeal blood system for the separation of substances in solutions via a semipermeable membrane. The system allows for volume controlled ultrfiltration and/or infusion of heparin through a blood pump by utilizing a standard double needle or optional single needle dialysis procedure.

[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 technology used to manufacture the product.

The components and materials used for the Dialog Dialysis Machine do not come into direct patient contact.

SUBSTANTIAL EQUIVALENCE:

The Dialog Dialysis Machine is identical in materials, form, and intended use to the HD Secura Dialysis Unit currently marketed by Organon Teknika and the 480 High-Flow Ultrafiltration Control Dialysate marketed by CD Medical. There are no new issues of safety or effectiveness raised by Dialog Dialysis Machine.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1998

Mr. Mark S. Alsberge
Director, Regulatory Affairs
B. Braun Medical Inc.
824 12th Avenue
Bethlehem, Pennsylvania 18018-0027

Re: K963440
Dialog Dialysis Machine
Dated: May 27, 1998
Received: June 5, 1998
Regulatory Class: III
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Alsberge:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Dialog Dialysis Machine

Indications For Use:

The intended use of the device is for Volume controlled ultrafiltration and infusion of heparin through a blood pump for the treatment of renal failure or toxic conditions. This device may be used for High-Flux Hemodialysis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K963440

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)