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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

September 2, 1997

CONTACT: Mark S. Alsberge, Regulatory Affairs Director

PRODUCT NAME: Diapact CRRT

TRADE NAME: Dialyzer , High Permeability with or Without Sealed Dialysate System

CLASSIFICATION NAME:

Gastroenterology & Urology -
Class III, 78 KDI, Single Patient Dialysate
Delivery System
21 CFR 876.5820

SUBSTANTIAL EQUIVALENCE[1] TO:

510 (k) Number	Applicant	Description
K900105	Cobe Laboratories, Inc.	SPECTRA - Blood Component Separator Therapeutic
K946279	Cobe Renal Care Inc.	PRISMA - CFM - Continuous Fluid Management System

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 DIAPACT CRRT - (Continuous Renal Replacement Therapies). It is an extracorpeal blood purification system intended to be used for acute renal failure. The system provides high flow continuous renal replacement therapies, emergency intermittent dialysis treatment and plasmapheresis.

[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.

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SUBSTANTIAL EQUIVALENCE:

The DIAPACT CRRT is identical in materials, form, and intended use to the PRISMA - CFM Continuous Fluid Management System and the SPECTRA - Blood Component Separator Therapeutic currently marketed by Cobe. There are no new issues of safety and effectiveness raised by Diapact CRRT.

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 cGMP"s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1998

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

Re: K973322
Diapact CRRT
Dated: August 11, 1998
Received: August 14, 1998
Regulatory Class: III
21 CFR 876.5860/Product code: 78 KDI
unclassified/Product code: 78 LKN

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): K973322

Device Name: Diapact CRRT

Indications For Use:

Diapact is an extracorpeal blood purification system intended to be used for acute renal failure. The system provides high flow continuous renal replacement therapies, emergency intermittent dialysis treatment and plasmapheresis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973322

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

(Optional Format 1-2-96)