510K(k) SUMMARY

SUBMITTER:	**Gambro Healthcare 1185 Oak Street Lakewood, CO 80215 (303) 231-4436**
DATE PREPARED:	**October 27th, 1998**
DEVICE NAME:	**Gambro Dialysis Quality Monitor DQM 200**
CLASSIFICATION NAMES:	**In Vitro Urea Nitrogen Test System (75LFP)**
PREDICATE DEVICE:	**Baxter BioStat 1000 Urea Monitor**

Device Description:

The Gambro DQM 200 measures the urea concentration in the dialysis solution leaving the waste outlet of a dialysis machine. Measurements obtained by this device are used in the treatment of certain renal diseases for patients on hemodialysis.

The purpose of the Gambro DQM 200is to act as a clinical tool aiding the physician to evaluate the dialysis dose of a treatment. The DQM 200 performs a continuous urea measurement of the spent dialysate flow from a Cobe C3 machine, A Gambro AK 10 Machine, a Gambro AK 100/200 or a Gambro AK 100/200 ULTRA machine. From this measured data together with patient and treatment data provided by the operator of the DQM 200 derives clinical parameters to help define the dialysis dose. The urea measurement is achieved by catalyzing urea with the urease enzyme, with carbon dioxide gas present into ammonium ions and bicarbonate ions. The produced ions cause an increase in the electrical conductivity in proportion to the urea concentration.

Predicate Device:

The Gambro DQM 200 is substantially equivalent to the Baxter BioStat 1000 Urea Monitor – 510(k) Number K925581. Examination of the information pertaining to the Baxter BioStat 1000 Urea Monitor demonstrates that this device is substantially equivalent in composition, intended use, function and labeling to other urea monitors for the measurement of urea concentrations in spent dialysis solution with subsequent calculation of various urea kinetic parameters which are currently cleared for commercial distribution in the United States by the FDA.

CONFIDENTIAL INFORMATION

Indications for Use Statement:

The Gambro Dialysis Quality Monitor DQM 200 is to act as a clinical tool aiding the physician to establish a dialysis dose of treatment of the patient. The DQM 200 performs a continuous measurement of the spent dialysate flow from a dialysis machine. From this measured data together with patient and treatment data provided by the operator, the DQM 200 derives clinical parameters helpful to the physician in evaluating the dialysis dose.

This indication for use statement is essentially the same as the indication for use statement for the predicate device.

Technological Characteristics

Comparing the proposed device to the predicate device, both devices utilize the same methods and technique for measuring urea concentrations in spent solution exiting a hemodialysis machine. Both devices utilize software and established formulas to calculate various patient and treatment related, urea parameters. There are no significant differences.

Summary of Non-Clinical Testing:

In Vitro testing demonstrated that the device performs as intended and labeled

Clinical Testing:

Clinical testing demonstrated that the device performs as intended and labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 27 2000

Jeffrey R. Snideman, Ph.D.
Gambro Healthcare
7303 Glouchester Drive
Edina, Minnesota 55435

Re: K990039
Trade Name: Dialysis Quality MonitorGambro DQM 200
Regulatory Class: II
Product Code: LFP
Dated: December 6, 1999
Received: December 9, 1999

Dear Dr. Snideman:

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 legally marketed predicate 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF *KNOWN*):

DEVICE NAME: Dialysis Quality MonitorGambro DQM 200

INDICATIONS FOR USE:

Indications for Use: Gambro Dialysis Quality Monitor DQM 200

The Gambro Dialysis Quality Monitor DQM 200 is to act as a clinical tool aiding the physician to establish a dialysis dose of treatment of the patient. The DQM 200 performs a continuous measurement of the spent dialysate flow from a dialysis machine. From this measured data together with patient and treatment data provided by the operator, the DQM 200 derives clinical parameters helpful to the physician in evaluating the dialysis dose.

(Division Sign-Off)
Division of
K990039

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)
Concurrence of CDRH, Office of Device Evaluation **(ODE)**

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)