Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

5.0 510(K) SUMMARY

Submitter's Name	Gambro Renal Products, Inc.
Address	14143 Denver West Parkway, Suite 400 Lakewood, Colorado 80401
Establishment Registration Number	2087532
Date of Summary	March 16, 2009
Telephone Number **Fax Number**	(303) 542-5045 (303) 876-9264
Contact Person	Kae Miller, Regulatory Affairs Manager
Name of the Device	Exalis Software 1.15 Catalogue Number: 6041909
Common or Usual Name	Accessory to Hemodialysis Delivery System
Classification Name	Classification Name:-Hemodialysis System and accessories Device Class: II Product Code: 78 FKP Regulation Number: 876.5820
Indications for Use	Exalis is an integrated product able to acquire; process and supply data required when running a dialysis treatment. This software application makes it possible to insert, modify, acquire, display in textual and graphical form data about dialysis prescription, ongoing and performed dialysis treatments and patient personal data. Exalis is an accessory intended to be used with Gambro Phoenix Haemodialysis system (starting from software version 3.35) in a Chronic Dialysis Facility and at Limited Care Centers.
Identification of the Legally Marketed Device (Predicate Device)	CyberRen® Clinical Data Management System 510(k) Number: K970989 Classification Name: Hemodialysis System and accessories Device Class: II Product Code: 78KPF, 78FKP Regulation Number: 876.5820

JUN - 5 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kae Miller
RA Manager, US
Gambro, Inc.
14143 Denver West Parkway, Suite 400
LAKEWOOD, CO 80401

JUN - 5 2009

Re: K083158
Trade/Device Name: Exalis Software 1.15
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 22, 2009
Received: May 22, 2009

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

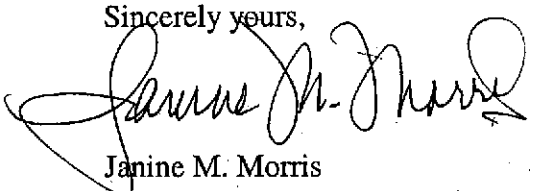
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

Indications for Use

510(k) Number (if known): K083158

Device Name: Exalis Software 1.15

Indications for Use:

Exalis is an integrated product able to acquire, process and supply data required when running a dialysis treatment. This software application makes it possible to insert, modify, acquire, display in textual and graphical form data about dialysis prescription, ongoing and performed dialysis treatments and patient personal data.

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083158