JUN - 7 2007

Edwards Lifesciences
Edisonstrasse 6
85716 Unterschleissheim
Germany
Telephone: +49 89 95475 203
Fax: +49 89 95475 301

Edwards

510(k) Summary as required by 21 CFR 807.92 (c)

Date Summary Prepared:

January 31, 2007

Owner's Name:

Edwards Lifesciences Services GmbH

Address:	Edisonstrasse 6
	Unterschleissheim
	D-85717
	Germany
Tel:	+49 89 95475 203
Fax:	+49 89 95475 301
Contact Person:	Robert Madjno
	Director of Regulatory and Quality Affairs

510(k) Contact Persons:

Neil R. Armstrong
Regulatory Affairs Advisor
MeddiQuest Limited
Business and Technology Centre
Bessemer Drive
Stevenage
SG1 2DX
United Kingdom
Tel: +44 1763 222505
Fax: +44 1763 222049

or

Robert Madjno
Director of Regulatory and Quality Affairs
Edwards Lifesciences Services GmbH
Edisonstrasse 6
85716 Unterschleissheim
Germany
Tel: +49 89 95475 203
Fax: +49 89 95475 301

Type of 510(k):
Traditional

Classification Name:
High Permeability Hemodialysis Systems 78 KDI

Common/Usual Name:
Hemofiltration System

Proprietary Name:
Edwards Aquarius System

Establishment Registration Number:
The device will be manufactured for:
Edwards Lifesciences Services GmbH
Edisonstrasse 6
Unterschleissheim
D-85717
Germany
Establishment Registration Number applied for
by
MeSys GmbH
Beneckallee 30
Hannover
D-30419
Germany
Establishment Registration Number 9680719

Substantial Equivalence:

The Edwards Aquarius system is based on product manufactured by MeSys, which has also been used as the basis for the Baxter Accura System - K021615.

The Edwards Aquarius system has been marketed and developed in Europe for six years. The software has been significantly improved from that used in the Baxter Accura System and the hardware has been similarly improved reflecting the European field experience.

The Edwards Aquarius system is substantially equivalent in design, use and materials to the:

Baxter Accura System	K021615
Gambro Prisma System	K993064, K981681, K946279
B. Braun Diapact	K973322

The Edwards Aquarius system is made of the same materials as the Baxter Accura System (K021615).

The Edwards Aquarius system is manufactured by the same processes as the Baxter Accura System (K021615).

Comparison of Technological Features:

Feature	Actual Device: Edwards Aquarius	Predicate Device A: Baxter Accura System, K021615
Housing	Front panel	Different - repositioning
	Rear panel	Same, except color
	Interior (including card slots)	Same, except ADU and new BLD
Cart	Trolley on rollers equipped with brakes	Same, except different tube surface treatment
Computer systems		Same
Display	Solid State Color monitor	Same
	Monitor casing	Same
Motherboard		Same, except Accura battery
Master extension	Extension for ADU	Not available

Feature	Actual Device: Edwards Aquarius	Predicate Device A: Baxter Accura System, K021615
board		
Serial connector (RS232)	**Optical connector**	Same
Power supply		Same
Wiring	Cable form	Same, except ADU connection
Blood pump with rotation sensor		Same
Heparin pump	Hardware and Software	Different
Arterial pressure sensor		Same
Prefilter pressure sensor		Same
Filtrate pressure sensor	Membrane unit holder	Same
	Pressure transducer	Same
	Evaluation electronics	Same with later Accura SW ver. 2.05
	Software	Same
Bubble trap and venous tube clamp		Same
Blood leak detector	Housing	Same
	Evaluation electronics	Different, change to SMD technology
	Software	Different, changed values for alarm limits
Predilution pump		Same
Filtrate pump		Same
Postdilution pump		Same
Substitution fluid weighing scales	Weighing scales hooks	Different, more ergonomic with Aquarius
	Weighing device	Same
	Evaluation electronics (18 bit converter)	Different, change to SMD technology
	Software	Same
Filtrate weighing scales	Weighing scales hooks	Different, more ergonomic with Aquarius

Feature	Actual Device: Edwards Aquarius	Predicate Device A: Baxter Accura System, K021615
	Weighing device	Same
	Evaluation electronics (18 bit converter)	Different, change to SMD technology
	Software	Same
ADU	**Pressure monitoring and pump**	**Not available at Accura**
Heater	Mechanical structure	Same
	Plate heater	Same
	Temperature Monitor	Different, integrated to heparin pump housing
	Driver and evaluation electronics	Different, change to SMD technology
	Software	Same
AC Power	Operating Voltage	Same
	Input Line Current	Same

Description of Product:

The Edwards Aquarius System needs to be used in conjunction with a tubing set and a filter to provide Hemofiltration treatment to the patient.

The tubing set has already been the subject of a PreMarket Notification, K063293 Edwards Aqualine Sterile Tubing Sets, and the filter will be the subject of a separate PreMarket Notification, currently in preparation.

The Aquarius system is an Automated Fluid Balance Monitor, designed to be used with various extracorporeal treatments in the field of renal replacement therapies or plasma therapies. All therapies must be prescribed by a physician.

The Aquarius system is divided into three circuits: the extracorporeal (blood) circuit, the substitution/dialysate circuit and the filtrate circuit.

Toxic substances are removed by filters and clean blood is returned to the patient.

The Aquarius system allows the patient to be positioned left or right of the instrument.

The Aquarius system uses two scales to accurately measure and precisely balance filtration and substitution volumes.

Heparin may be supplied to the extracorporeal circuit via an anticoagulant pump (Heparin pump). The prescribing physician may select continuous or intermittent options.

The Aquarius protective system is designed as a 2-channel system to protect the patient from foreseeable danger.

At the back of the scale system a removable hand-crank is mounted. This can be used to manually turn the blood pump in case a pump stops.

The Aquarius system is portable. It has a wheeled base connected with a handle to move or carry the Aquarius.

Significant Physical and Performance Characteristics:

Fluids Management	**Low Blood Flow**	**Regular Blood Flow**
Pump accuracy	±5%	±5%
Blood	10 to 200 ml/min by 2 ml/min	30 to 450 ml/min by 10 ml/min
Pre-dilution	0-100 to 6000 ml/h	0-100 to 10000 ml/h
Post-dilution	0-100 to 4000 ml/h	0-100 to 10000 ml/h
Dialysate	0-100 to 10000 ml/h (CVVHD only)	0-100 to 10000 ml/h
Filtrate	0-100 to 11000 ml/h	0-100 to 12000 ml/h
Net fluid loss	0-10 to 1000 ml/h by 1 ml	0-10 to 2000 ml/h
Heparin pump accuracy	± 0.2 ml/h	± 0.2 ml/h
Heparin pump settings	0-15 ml/h by 0.5 ml/h	0-15 ml/h by 0.5 ml/h
Heparin syringe size	30 or 50 ml	30 or 50 ml
Bolus function	0.5 to 2.5 ml by 0.5 ml bolus increment	0.5 to 2.5 ml by 0.5 ml bolus increment
Scales	**Low Blood Flow**	**Regular Blood Flow**
Fluid balance alarm	20g	50g
Substitution scale capacity	0-30kg (max. load: 23kg)	0-30kg (max. load: 23kg)
Filtrate scale capacity	0-30kg (max. load: 23kg)	0-30kg (max. load: 23kg)
Fluid warmer	**Low Blood Flow**	**Regular Blood Flow**

Accuracy	± 0.3 °C	± 0.3 °C
Working range	Off or 35°C to 39°C by 0.5°C	Off or 35°C to 39°C by 0.5°C

Pressure Monitoring	
Sensor accuracy	± 5 mmHg
Access	-250 to +200 mmHg
Return	-50 to +350 mmHg
Pre-filter	-150 to +500 mmHg
Filtrate	-250 to +400 mmHg
Degassing unit	
Pressure	-300 to +30 mmHg
Gas removal Max.	10 ml/min
Weight and Dimensions	
H x W x D	170 cm x 50 cm x 60 cm
Floor space	Approx. 55 cm (W) x 65 cm (D)
Weight	Approx. 75 kg
Power Requirements	
European voltage	230 V (alternating voltage) ± 10%, 50 Hz
Power consumption	500 VA
North American voltage	115 V (alternating voltage) ± 10%, 60 Hz
North American consumption	500 VA
Monitor / Detection Parameters	
Air detector	Ultrasonic measurement
Blood leak detector	2 or 4 ml blood/1l filtrate at HCT 32%
Display monitor	10.4" TFT color
Processors	2- CPU 80, 1- Intel

Intended use:

The Edwards Aquarius System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Edwards Aquarius system may also be used in Therapeutic Plasma Exchange (TPE) therapies.

The Edwards Aquarius system is indicated for use in a clinical setting and not for home use.

Testing Summary:

Electrical Safety and Electromagnetic Compatibility:

Testing has been conducted following the IEC 60601 series of standards, which are FDA recognized voluntary consensus standards.

Bench Testing:

Comparative bench testing of the Edwards Aquarius System and Baxter Accura System, using an Edwards Aqualine Sterile Tubing Set K063293, is included. This concludes that the two machines have substantially equivalent performance.

Animal Testing:

No animal testing is included.

There are no patient or patient's blood contacting materials.

Clinical Testing:

No clinical testing is included.

Other Information:

A summary of European surveillance and vigilance activities is included.

Currently approximately 1,500 machines have been placed on the European market and it is estimated these now (2006 figures) perform approximately 64,000 treatments per year (based on sales of tubing sets).

Vigilance	2002	2003	2004	2005	2006	TOTAL
NEAR INC	22	0	2	0	2	26
INCIDENTS	0	0	1	0	0	1

Robert Madjno
Director of Regulatory and Quality Affairs
Edwards Lifesciences Services GmbH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Edwards Lifesciences Services GmbH
c/o Neil R. Armstrong
Regulatory Affairs Advisor
MeddiQuest Limited
Business and Technology Centre
Bessemer Drive
Stevenage SG1 2DX
UNITED KINGDOM

JUN - 7 2007

Re: K070320
Trade/Device Name: Edwards Aquarius System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 14, 2007
Received: May 21, 2007

Dear Mr. Armstrong:

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.

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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070320

Device Name: Edwards Aquarius System

Indications for Use:

The Edwards Aquarius System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Edwards Aquarius system may also be used in Therapeutic Plasma Exchange (TPE) therapies.

The Edwards Aquarius system is indicated for use in a clinical setting and not for home use.

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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070320