

AUG 31 2000

510(k) Premarket Notification

K99/864

JOSTRA MEDIZINTECHNIK AG – RotaFlow Centrifugal Pump System

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

COMPANY NAME AND CONTACT PERSON

May 21, 1999

Jostra Medizintechnik AG
Hechinger Straße 38
72145 Hirrlingen
Germany

Kathy Johnson, Product Manager
tel. (610)932-7365
fax (610)932-7366

DEVICE NAME

RotaFlow Centrifugal Pump System
Magnet Adapter MA-32
RotaFlow Centrifugal Pump RF-32 / RF-32F
Flowprobe FP-32E

COMMON NAME

Cardiopulmonary Bypass Pump Console,
Magnet Adapter
Centrifugal Blood Pump
Cardiovascular Blood Flowprobe

CLASSIFICATION NAME

Control, Pump Speed, Cardiopulmonary Bypass,
Adapter, Stopcock, Manifold, Fitting,
Pump, Blood, Non-roller-type, Cardiopulmonary Bypass,
Flowprobe, Blood, Cardiovascular

PREDICATE DEVICE OR LEGALLY MARKETING DEVICE

Medtronic Bio-Medicus Bio-Console Model 550
Medtronic Bio-Medicus Bio-Pump Centrifugal Blood Pump BP 80
St. Jude Medical Pulse 2100 Centrifugal Pump Interface
Medtronic Bio-Probe DP-38

DEVICE DESCRIPTION

The RotaFlow Centrifugal Pump System includes both hardware and disposables.
The RotaFlow Centrifugal Pump System includes the following components:

RotaFlow Centrifugal Pump System (= RotaFlow System)	
1. Components to be used in combination with the RotaFlow Console:	
1.1 Hardware	RotaFlow Console RFC 20-970 RotaFlow Drive Unit RFD 20-973 RotaFlow Emergency Drive RFE 20-976
1.2 Disposable	RotaFlow Centrifugal Pump RF-32
2. Components to be used in combination with the Bio-Medicus Console:	
2.1 Hardware	Magnet Adapter MA-32
2.2 Disposables	RotaFlow Centrifugal Pump RF-32F
	External Flow Probe FP-32E

INTENDED USE

The RotaFlow Centrifugal Pump System is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS

Table 1. Comparison between RotaFlow System (Hardware) and Medtronic Bio-Medicus Bio-Console Type 550

Name of Product	RotaFlow System (Hardware)	Medtronic Bio-Medicus Bio-Console Model 550
Power supply Mains	230 V~/ 50 Hz Stand Alone + 24 Volt Console HL-20 + 24 Volt Drive Unit	220-240 Vac with 50-60 Hz
Batteries Console:	+ 24 V, NiCd	Two, series connected, 12 Vdc lead-acid gel; rechargeable
Weight	app. 14.400 kg Console	23.000 kg (50 lbs.)
Measurements LxWxH/Size	179 x 385 x 243 mm Console	420 x 230 x 360 mm

Table 2. Comparison between RotaFlow Centrifugal Pump RF-32 / RF-32F and Medtronic Bio-Medicus Bio-Pump Centrifugal Blood Pump BP 80

Name of Product	RotaFlow Centrifugal Pump RF-32 / RF-32F	Bio-Pump Centrifugal Blood Pump BP-80
Priming Volume	32 ml	80 ml
Inlet/Outlet I. D.	9,5 mm (3/8 inches)	9,5 mm (3/8 inches)
Maximum Operating Pressure	750 mmHg	900 mmHg
Surface Area	190 cm ²	590 cm ²
Rotor Diameter	50 mm	79 mm
System	Flowchannel	Vortex rotors
Connectors	3/8"	3/8"

Name of Product	RotaFlow Centrifugal Pump RF-32 / RF-32F	Bio-Pump Centrifugal Blood Pump BP-80
materials:		
Housing	polycarbonate	polyacryl
Rotor	polycarbonate	polyacryl
Connector	polycarbonate	polyacryl
Callote	polyethylene	unknown
Ball	sapphire	unknown
Magnet	neodymium	unknown
in.- and outlet caps 3/8"	HDPE	unknown

SUMMARY OF PERFORMANCE DATA

The following tests were performed to demonstrate substantial equivalence between the RotaFlow Centrifugal Pump System and predicate devices (Medtronic, St. Jude):

Disposables:

- Function and Load testing in continuous and pulsatile mode
- Verification of the flow-pressure curves
- Mean Transit Time
- Heat generation
- Stagnant blood zones
- Validation Flowprobe

Magnet Adapter:

- Endurance Test
- Heat Generation
- Magnetic Clutch

RotaFlow System (Hardware):

- Clinical Assessment
- Functional Safety
- EMC
- Construction Safety
- Mains and Battery Operation
- Interface Testing Console with Jostra Heart-Lung Machine
- Emergency Unit Accuracy Testing
- Software Validation

The above listed testings demonstrated that the RotaFlow Centrifugal Blood Pump System is substantial equivalent to the compared predicate devices from Medtronic and St. Jude.

Biocompatibility and Blood Damage Testing:

Biocompatibility testing of the RotaFlow Centrifugal Pump was performed in accordance with the FDA Blue Book Memorandum - #G95-1 and Biological Evaluation of Medical Devices Guidance – International Standard ISO 10993-1, and in accordance with United States Pharmacopeia – XXIII.

Based on the results of the biocompatibility testing performed, the RotaFlow Centrifugal Pump was determined to be biocompatible and nontoxic and, therefore, safe for its intended use.

Blood Damage Testing has also been performed in comparison to the predicate device.

Sterility:

Sterilization of the RotaFlow Centrifugal Pump and Flowprobe have been validated to assure a sterility assurance level (SAL) of 10^{-6} .

EtO sterilized RotaFlow Pump is sterilized in accordance with the American National Standards Institute, Inc. (ANSI) standard ANSI/AAMI/ISO 11135-1994 (Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization).

EtO Residuals:

RotaFlow Centrifugal Pump meets the limits for residual concentrations of ethylene oxide (<25 ppm), ethylene chlorohydrin (<25 ppm), and ethylene glycol (< 250 ppm) as published in ANSI Standard Number ANSI/AAMI/ISO 10993-7 (Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals).

Pyrogens:

Routine pyrogen testing is performed using the Limulus Amebocyte Lysate (LAL) method. Product testing and release criteria (less than 20 EU/ml) is in accordance to the December 1987 Guideline issued by the Food and Drug Administration, office of Compliance („Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices“).

Conclusion

Performance, functional, and biocompatibility testing demonstrated that the RotaFlow Centrifugal Pump System is substantially equivalent to the named predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Jostra Incorporated
c/o Ms. Kathy Johnson
Product Manager
2035 Sunset Lake Road
Newark, DE 19702

Re: K991864
Rotaflow Centrifugal Pump System
Regulatory Class: III (three)
Product Code: KFM
Dated: August 14, 2000
Received: August 15, 2000

Dear Ms. Johnson:

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.

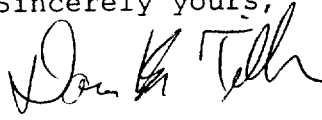
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Kathy Johnson

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) 594-4648. 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" (21CFR 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,

for 

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): not assigned

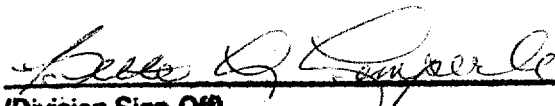
Device Name: RotaFlow Centrifugal Pump System

Indications for Use „RotaFlow Centrifugal Pump System“:

The RotaFlow Centrifugal Pump System is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off) (Optional Format 3-10-98)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991864