K031544

510(k) Summary of Safety and Effectiveness

Submitted by: Jostra AB
Annedalsvägen 2B
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AUG 7 2003

Contact Person: LeAnn Latham
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Date prepared: 2003-04-30

Device Trade Name: Jostra HCU 30

Common/Usual Name: Heater-Cooler Unit

Classification Names: Controller, Temperature, Cardiopulmonary Bypass

Predicate Device: Sarns temperature control and monitor system (TCM II)
K883603

Device Description:

The Jostra Heater-Cooler Unit HCU 30 supplies temperature-controlled water for cardioplegia heat exchangers, for blood heat exchangers in extra corporeal circulation and for blankets with which patients can be warmed or cooled.

The water temperature is adjustable from 1°C to 41°C. A 26 litre tank with ice and approx. 1°C cold water assures quick cooling of the patient.

Two independent circuits with separate temperature controls can be attached (the main side has two connections).

A safety system monitors the regulation in order to prevent the temperature from rising above 42°C.

Indications for use:
The Jostra HCU 30 is intended to circulate water through heat exchange circuits to warm or cool a patient during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

Technical Characteristics Comparison:

Name of Product	Jostra HCU 30	Terumo TCM II
Applications	*Total-body heating cooling,, independent cardioplegia (Dual hyper-hypothermia system)*	*Total-body heating cooling,, independent cardioplegia (Dual hyper-hypothermia system)*
Intended use	The Jostra HCU 30 is intended to circulate water through heat exchange circuits to warm or cool a patient during short duration cardiopulmonary bypass procedures lasting 6 hours or less.	The Sarns TCM II is indicated for controlling and monitoring patient temperature.
Where used	Hospital	Hospital
Physical Dimensions		
Dimensions (HxWxD)	42 x 18 x 21 in. (1060 x 465 x 525 mm)	34 x 20 x 30 in. (876 x 508 x 749 mm)
Floor space	380 sqin. (0.24 sqm)	600 sqin. (0.28 sqm)
Weight	ca. 267 lbs (121 kg) full	ca. 368 lbs (175 kg) full
	ca. 209 lbs (95 kg) empty	ca. 294 lbs (133 kg) empty
Temperature control		
Display	Full graphic display	Seven segment displays
Control range	1°C - 41°C (both circuits)	0°C – 42°C (for the main circuit), cardioplegia circuit: ice water only
Setting resolution	0,1°C	1°C
Measurement accuracy	±0.3°C	±0.3°C
Cooling system		
Method	Compressor, ice-making	Compressor, ice-making
Tank volume	7 gal. (26 litres)	9 gal. (34 l) main tank 1.2 gal. (4.5 l) cplg tank
Initial cooling capacity	6250 kJ/h	not specified
Continuous cooling capacity	4270 kJ/h (1186 W)	4320 kJ/h (1200 W)
Max cooling capacity	10520 kJ/h	not specified
Heating System		
Method	Electrical heater (2 units)	Electrical heater (2 units)
Capacity	3180 W (230 V) 1800 W (115 V)	1550 W (220 V) 2000 W (115 V)
Circulation		
Method	Pressure pump (2 units)	Pressure pump (2 units)
Number of connectors	6 (Two patient circuits with the same temperature and one independent cardioplegia circuit)	6 (Two patient circuits with the same temperature and one independent cardioplegia circuit)
Flow capacity, patient circulation	adjustable ca. 2.6-6.1 gal/min (10-23 l/min)	5.5 gal/min (21 l/min)
Flow capacity, cardioplegia circulation	min. 1.8 gal/min (7.0 l/min)	2.1 gal/min (7.8 l/min)
Maximum pressure, patient circulation	ca. 34.8 psi (1800 mmHg)	ca. 15.0 psi (700 mmHg)
Maximum pressure, cardioplegia circulation	ca. 13.1 psi (675 mmHg)	ca. 7.5 psi (386 mmHg)

Performance testing included:
The following performance tests were done in order to demonstrate that the requirements in the Requirement Specification were met.

- Heating mode test
- Cooling mode test
- Cleaning cycle test
- Alarm function test
- Interface test with RCU30 and HL30
- Reliability test
- Pressure regulation test
- Flow capacity test

Constructional Safety testing included:
The following tests were done in order to demonstrate that the legal requirements in the Requirement Specification were met.

- Electrical Safety
- Electromagnetic compatibility EMC
- Package and Transportation

Conclusion:
Performance and functional testing demonstrate that the Jostra HCU-30 is substantially equivalent to the claimed predicate devices in intended use, principles of operation, materials, design, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2003

Jostra Corp.
c/o Ms. LeAnn Latham
2828 N. Crescent Ridge Drive
The Woodlands, TX 77381

Re: K031544
Heater Cooler Unit HCU-30
Regulation Number: 870.4250
Regulation Name: Temperature Controller
Regulatory Class: Class II (two)
Product Code: DWC
Dated: April 30, 2003
Received: May 16, 2003

Dear Ms. Latham:

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 (PMA), 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 (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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

Device Name: Jostra Heater Cooler Unit HCU 30

Indications for Use:
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031544

(Optional Format 3-10-98)

Prescription Use Only