

K 9104017

SECTION II

AVECOR CARDIOVASCULAR INC.

AFFINITY BLOOD PUMP SYSTEM

AUG - 5 1997

SUPPORTING SUMMARY FOR 510 (k) NOTIFICATION

- 1. Date Prepared: September 30, 1996
- 2. Submitter: AVECOR Cardiovascular Inc.
13010 County Road 6
Plymouth, MN 55441
- 3. Contact: Dennis E. Steger
Director Regulatory Affairs/
Quality Assurance
(800) 328-3320
- 4. Device Name: Cardiopulmonary Bypass Roller-Type Pumps, Consoles and Bypass Pump Tubing have been classified by the Cardiovascular Device Classification Panel as Class II devices, as proposed in Section 870.4220/4370/4380/4390, Title 21 of the Code of Federal Regulations
- 5. Device Description & Comparison to Predicate Device:

To establish the substantial equivalency of the AVECOR Affinity Pump System to the Stockert Instrumente (Sorin) Pump design, specifications, materials, indications for use, and performance characteristics were compared.

DESIGN

The AVECOR Affinity Blood Pump System is intended for use in an extracorporeal perfusion circuit to pump blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

The AVECOR Cardiovascular Affinity Pump System consists of the Model 2000 Affinity Pump Console, Affinity Pump Rotor, Affinity Pump Holder, Affinity Pump Chamber, 5/8" Connecting Tube and an AVECOR venous reservoir with 5/8" outlet.

The AVECOR Affinity Blood Pump Console and components' shall conform with all the applicable requirements of IEC 601, UL 544 and will display the European Community CE marking.

The Affinity Pump Console, Model 2000 provides a system for controlling a variable speed pump motor and additional systems for monitoring flow rate, pump speed (RPM), pressure, timed events and battery status.

The AVECOR Affinity Pump has been designed to operate on the principles of a peristaltic pump for extracorporeal use. The pump consists of a polyurethane chamber incorporating polycarbonate inlet and outlet connectors, which fills passively due to the filling pressure exhibited by the fluid height in a reservoir. The peristaltic action of the rollers against the filled pump chamber results in forward flow. Flow rate is affected by the combination of reservoir volume, RPM's of the pump rotor and the total circuit resistance.

The Stockert Instrumente (Sorin) Pump Console Model No. 10-10-00, provides a system for controlling a variable speed pump motor and additional systems for monitoring flow rate, pump speed (RPM), pressure and timed events.

The Stockert Instrumente (Sorin) Pump is designed to operate on the principles of a peristaltic pump for extracorporeal use. The pump consists of a polyvinyl chloride tubing segment with polycarbonate connectors at each end. Flow rate is affected by the RPM's, of the pump rotor, total circuit resistance and the size of the tubing segment used.

SPECIFICATIONS & MATERIALS

A detailed comparison of specifications and materials can be found in Table 1. Specifications for the Stockert (Sorin) console are taken from Stockert's labeling.

Table 1
Pump Console
Comparison of Specifications

	<u>Affinity Console</u>	<u>Stockert Console</u>
Input Power	<ul style="list-style-type: none"> • 100 or 110-120 Vac, 50-60 Hz, • 220-240 Vac, 50-60 Hz 	<ul style="list-style-type: none"> • 100 or 110-120 Vac, 50-60 Hz • 220-240 Vac, 50-60 Hz
Internal Batteries	Yes	No (External Battery Pack Optional)
Case Dimensions	13" H x 7" W x 17" D	12" H x 7" W x 19" D
Weight	50 lb.	48 lb.

Pump Chamber Comparison of Materials

	<u>Affinity</u>	<u>Stockert (Sorin)</u>
Chamber	Polyurethane	Polyvinyl Chloride
Connectors	Polycarbonate	Polycarbonate
Protective Caps	PVC	PVC

INDICATIONS FOR USE

The Affinity Blood Pump System and the Stockert Instrumente (Sorin) Pump System are indicated for use in an extracorporeal perfusion circuit to pump blood during cardiopulmonary bypass procedures.

PERFORMANCE CHARACTERISTICS

The following tests were conducted by AVECOR to establish the safety and effectiveness of the Affinity Blood Pump System.

<u>Test Description</u>	<u>Location</u>
In Vitro Operating Characteristics	Section III
In Vitro Cellular Damage	Section III
Material Biocompatibility	Section IV
Sterility	Section V
Pyrogenicity	Section V
Sterilant Residuals	Section V
Software Validation & Verification	Appendix E

Protocols describing the test methods utilized in this application may be found in the appropriate Appendix.

The results indicate that the Affinity Blood Pump System is substantially equivalent in performance to the Stockert Instrumente (Sorin) Pump System.

BLOOD TRAUMA SUMMARY STATEMENT

Blood trauma testing shows that in all aspects evaluated (hemolysis, platelet and white cell response) the Affinity Blood Pump System and the Stockert Instrumente (Sorin) Pump System are equivalent.

CONCLUSION

WE HAVE CONSIDERED DESIGN, MATERIALS, INDICATIONS FOR USE, PERFORMANCE CHARACTERISTICS, ALONG WITH A DIRECT COMPARISON OF TEST RESULTS BETWEEN THE AFFINITY AND STOCKERT PUMP SYSTEMS IN OUR APPLICATION. IT IS BASED UPON THE REVIEW OF ALL OF THESE PARAMETERS THAT AVECOR CARDIOVASCULAR INC. DETERMINES THAT THE AFFINITY BLOOD PUMP SYSTEM IS SUBSTANTIALLY EQUIVALENT TO THE CURRENTLY MARKETED STOCKERT INSTRUMENTE (SORIN) BLOOD PUMP SYSTEM.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Dennis E. Steger
Director Regulatory Affairs/
Quality Assurance
Avecor Cardiovascular, Inc.
7611 Northland Drive
Minneapolis, Minnesota 55428

AUG - 5 1997

Re: K964017
AFFINITY™ Blood Pump System
Regulatory Class: II (Two)
Product Code: 74 DTQ
Dated: May 9, 1997
Received: May 12, 1997

Dear Mr. Steger:

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 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 requirement, 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 - Mr. Dennis E. Steger

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" (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/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

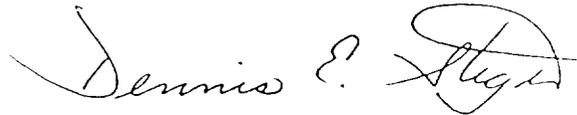
870.4370 - DWB II - Roller - type CPB Blood Pump

510(k) Number (if known): K964017

Device Name: AFFINITY Blood Pump System

Indications For Use:

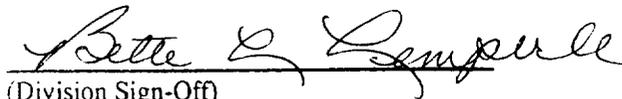
The Affinity™ Blood Pump System is intended to be used in an extracorporeal perfusion circuit to pump blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.



Dennis E. Steger
Director Regulatory Affairs/
Quality Assurance
AVECOR Cardiovascular Inc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K964017

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)