Confidential

K112372

CARDIOSAVE™ Intra-Aortic Balloon Pump
510(k) Summary
Prepared in accordance with 21 CFR Part 807.92

SEP 15 2011

GENERAL INFORMATION

Submitter's name and address: Cardiac Assist, MAQUET Cardiovascular LLC
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Mahwah, NJ 07430

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Date prepared: August 16, 2011

DEVICE INFORMATION:

Trade Name:	CARDIOSAVE™ Intra-Aortic Balloon Pump
Common/Generic Name:	Intra-aortic balloon and control system
Classification Name:	Intra-aortic balloon and control system
Regulation Number:	21 CFR 870.3535
Product Code:	DSP

PREDICATE DEVCE INFORMATION:

The CARDIOSAVE™ Intra-Aortic Balloon Pump is substantially equivalent in function and intended use to the CS300 Intra-Aortic Balloon Pump (K063525).

DEVICE DESCRIPTION AND INTENDED USE:

The CARDIOSAVE™ Intra-Aortic Balloon Pump (IABP) is a cardiac assist device. It supports the heart's left ventricle by increasing coronary perfusion and reducing left ventricular work. Coronary perfusion is increased by augmenting blood pressure during the diastolic phase of the cardiac cycle. This increase in aortic pressure promotes more blood flow through the coronary arteries. Left ventricular work is reduced by decreasing aortic end-diastolic pressure and reducing resistance to ventricular ejection, resulting in a decrease in blood pressure during the systolic phase of the cardiac cycle.

These beneficial effects are caused by the inflation and deflation of an intra-aortic balloon (IAB) in the patient's descending aorta. The balloon's inflation and deflation must be properly synchronized with the cardiac cycle. IAB inflation is initiated at the onset of diastole at the dicrotic notch and remains inflated through diastole. The IAB is then deflated at, or just prior to, the onset of systole and the balloon remains deflated throughout systole. Hence, the therapy is also referred to as counterpulsation. This is the same intended use as other IABPs.

TECHNOLOGICAL CHARACTERISTICS:

The CARDIOSAVE™ Intra-Aortic Balloon Pump (IABP) is substantially equivalent to the Datascope Corp CS300 IABP. The changes in the CARDIOSAVE™ IABP design essentially consist of both dimensional and weight reduction of the device, a change from a sealed lead acid battery to a "hot swappable" Lithium Ion battery, minor user interface improvements, material modification to two internal components of the IABP, an improved lead fault detection, elimination of the manual fill capability due to the dissolution of the pediatric IAB Catheter market (rendered obsolete through other technology), and modification to the Autofill process from a volume based process to a pressure based process.

NON-CLINICAL TESTS:

The CARDIOSAVE™ Intra-Aortic Balloon Pump complies with the voluntary standards identified in Section 3 of this submission. Cardiac Assist, MAQUET Cardiovascular LLC's development process required that the following activities be completed during the development of the CARDIOSAVE™ Intra-Aortic Balloon Pump:

- Requirements specification review
- Hardware and software testing
- Code design and code reviews
- Environmental testing
- Safety testing
- Performance testing
- Hardware and software validation

CLINICAL TESTS:

No clinical evaluation of the modified device was conducted or required.

CONCLUSION:

Based upon the information submitted in this Special 510(k) premarket notification, MAQUET's CARDIOSAVE™ Intra-Aortic Balloon Pump is substantially equivalent to the currently marketed CS300 Intra-Aortic Balloon Pump (K063525). The CARDIOSAVE™ Intra-Aortic Balloon Pump is similar to the predicate device in the intended use, the fundamental scientific technology of the device, and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

MAQUET Cardiovascular, LLC.
c/o Mr. Helder A. Sousa
Regulatory Affairs Program Manager
1300 MacArthur Blvd.
Mahwah, NJ 07430

SEP 15 2011

Re: K112372
Trade/Device Name: CARDIOSAVE ™ Intra-Aortic Balloon Pump
Regulatory Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon and Control System
Regulatory Class: III (three)
Product Code: DSP
Dated: August 16, 2011
Received: August 17, 2011

Dear Mr. Sousa:

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 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

510(k) Number (if known): K112372

Device Name: CARDIOSAVE™ Intra-Aortic Balloon Pump

Indications For Use:

The CARDIOSAVE™ Intra Aortic Balloon Pump is an electromechanical system used to inflate and deflate intra-aortic balloons. It provides temporary support to the left ventricle via the principle of counterpulsation. The intra-aortic balloon is placed in the descending aorta, just distal to the left subclavian artery. Once the balloon is positioned, the pump is adjusted to trigger in synchrony with the ECG or arterial pressure waveform to ensure that inflation and deflation occur at the appropriate points during the cardiac cycle.

The target population is adult. The balloon pump is intended for use in the health care facility setting.

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

(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 Devices
510(k) Number K112372