SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter
510(k) Summary
Prepared in accordance with 21 CFR Part 807.92

SEP - 9 2011

GENERAL INFORMATION

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

15 Law Drive
Fairfield, NJ 07004

Contact person and telephone number: Helder A. Sousa
Regulatory Affairs Program Manager

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Date prepared: August 10, 2011

DEVICE INFORMATION:

Trade Name:	SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter and Accessories
Common/Generic Name:	Intra-Aortic Balloon Catheter (IAB)
Classification Name:	Intra-Aortic Balloon Catheters (IABs)
Regulation Number:	21 CFR 870.3535
Product Code:	DSP

PREDICATE DEVICE INFORMATION:

The SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter is substantially equivalent in function and intended use to the SENSATION® 7Fr. IAB Catheter (K063525) and MEGA™ 8Fr. IAB Catheter (K091449).

DEVICE DESCRIPTION AND INTENDED USE:

The SENSATION® PLUS 8 Fr. 50cc IAB Catheter (SENSATION Plus) is an enhanced SENSATION 7Fr IAB Catheter which includes a catheter with accessories, an insertion kit and two STATLOCK® IAB Stabilization Devices. This device incorporates the fiber optic technology of the SENSATION 7Fr IAB Catheter with the increased membrane volume and French size of the Mega™ 50cc 8Fr. IAB Catheter (K091449). The SENSATION® Plus Insertion kit contains the same components as currently used with the Mega 50cc 8Fr IAB Catheter with the sole exception that the SENSATION® Plus Insertion Kit does not contain two lengths (4-ft) of pressure tubing, due to the fact that pressure monitoring is accomplished via the fiber optic cable. In addition, the SENSATION® Plus Insertion Kit contains six extender tubing clips, similar to the predicate SENSATION® Insertion Kit.

The SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter 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 the intra-aortic balloon (IAB) Catheter placed in the patient's descending aorta just below the subclavian artery. The balloon's inflation and deflation must be properly synchronized with the cardiac cycle. IAB Catheter inflation is initiated at the onset of the diastole at the dicrotic notch and remains inflated through diastole. The IAB Catheter 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 IAB Catheters.

TECHNOLOGICAL CHARACTERISTICS:

The SENSATION™ PLUS 8Fr. 50cc IAB Catheter has the same fiber-optic pressure sensor technology as the predicate SENSATION 7Fr. IAB Catheter, and the same membrane volume and French size as the MEGA 8Fr. 50cc IAB Catheter.

NON-CLINICAL TESTS:

The SENSATION PLUS IAB Catheter 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 SENSATION PLUS IAB Catheter:

- Requirements specification review
- Performance testing
- Biocompatibility testing
- Sterility testing
- Shelf life testing
- Design validation

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed IAB Catheters.

CLINICAL TESTS:

There was no clinical evaluation of the modified device.

Conclusion:

Based upon the information submitted in this Special 510(k) premarket notification, MAQUET's SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter is substantially equivalent to the currently marketed SENSATION® 7Fr. IAB Catheter (K063525) and MEGA™ 8Fr. IAB Catheter (K091449). The SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter is similar to the predicate devices in the intended use and the

fundamental scientific technology of the device. The design verification and validation testing established that the SENSATION Plus IAB Catheter is safe and effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Datascope Cardiac Assist
c/o Ms. Helder A. Sousa
Regulatory Affairs Program Manager
1300 MacArthur Blvd
Mahwah, NJ 07430

SEP - 9 2011

Re: K112327
SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter and Accessories
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic Balloon and Control System
Regulatory Class: Class III
Product Code: DSP
Dated: August 10, 2011
Received: August 12, 2011

Dear Ms. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

K112327

Indications For Use

510(k) Number (if known): K112327

Device Name: SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter and Accessories

Indications For Use: MAQUET's SENSATION™ PLUS 8Fr. 50cc Intra-Aortic Balloon Catheter and Accessories have the following indications for use:

- Refractory Unstable Angina.
- Impending Infarction.
- Acute Myocardial Infarction.
- Refractory Ventricular Failure.
- Complications of Acute MI (ie. Acute MR or VSD or papillary muscle rupture)
- Cardiogenic Shock.
- Support for diagnostic, percutaneous revascularization and interventional procedures.
- Ischemia related intractable ventricular arrhythmias.
- Septic Shock.
- Intraoperative pulsatile flow generation.
- Weaning from cardiopulmonary bypass.
- Cardiac support for non-cardiac surgery.
- Prophylactic support in preparation for cardiac surgery.
- Post-surgical myocardial dysfunction/low cardiac output syndrome.
- Myocardial Contusion.
- Mechanical bridge to other assist devices.
- Cardiac support following correction of anatomical defects

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K112327