JAN 12 2009

510(k) Summary

K082746 – Insightra Ultra IABP Catheter Kit

a. Submitter

Applicant Name: Insightra Medical
15560-C Rockfield Boulevard
Irvine, CA 92618

Contact Person: Tom Colonna
Date Summary Prepare: December 22, 2008

b. Device Information

Trade Name: Ultra IABP Catheter Kit
Common Name: Intra-aortic balloon catheter and insertion kit
Classification Name: Intra-aortic balloon and control system (21 CFR 870.3535)
Product Code: 74 DSP

c. Predicate Devices

Abiomed SupraCor Balloon Catheter (K062582)
Datascope 7.5Fr IAB Catheter and Accessories (K041281)

d. Device Description

The Insightra Ultra IABP Catheter Kit is a 7 French catheter available with either a 40, 35, 30, 25, or 20 cc balloon. The catheter has two lumens and is designed to provide counterpulsation cardiac assist therapy. The outer lumen is a channel for helium used to inflate and deflate the balloon. The inner lumen is used for a guidewire and blood pressure measurement. It is packaged as a convenience kit with accessories (one-way valve, 50 cc syringe, guide wires, introducer needle, dilator, pressure tubing, Datascope & Arrow adaptors).

The balloon inflation and deflation cycle is synchronized (using a commercially available control console) with the ECG or arterial pressure to provide counterpulsation synchronized with the heartbeat. It is intended to increase coronary perfusion, decrease the workload of the left ventricle and allow healing of the myocardium.

e. Intended Use:

The Ultra IABP Catheter is used for emergency mechanical left heart assist in conjunction with an IAB catheter pumping circuit. The device is placed in the descending aorta just below the subclavian artery and is intended to improve cardiovascular function during the following situations:

- Refractory unstable angina
- Impending infarction
- Post infarction angina
- Refractory left ventricular failure
- Complications of acute MI (*i.e.*, acute MR or VSD or papillary muscle rapture)
- Cardiogenic shock

- Support for diagnostic percutaneous revascularization and interventional procedures
- Ischemic 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
- Cardiac contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects.

f. Technological Characteristics and Comparison to Predicate Devices

The Ultra IABP Catheter Kit is of similar design and made of materials commonly used in other marketed balloon catheters. The insertion kit contains instruments commonly provided for insertion of an IAB Catheter.

Table 1 provides a comparison of the Ultra IABP Catheter with the predicate balloon catheters. This table illustrates the equivalency of the Ultra IABP Catheter with the predicates.

Table 1 – Comparison Table for Ultra IABP Catheter Kit

	Insightra Ultra IABP	Datascope 7.5F IAB	Abiomed SupraCor IAB
510(k) Clearance	This submission	K041281	K062582
Number of Lumens	2	2	2
Catheter Outside Diameter (Fr.)	8	7.5	7
Balloon shape	Cylindrical	Cylindrical	Cylindrical
Balloon lengths (mm)	170, 180, 195, 225, 255	165, 221, 258	260
Balloon volumes (cc)	20, 25, 30, 35, 40	25, 34, 40	40
Balloon Diameters (mm)	13.5, 14.5	15	Unknown
Effective Catheter Length (mm)	700	723	720
Inflation Medium	Helium	Helium	Helium
Sterilization	EtO	EtO	EtO

g. Pre-Clinical Test Results:

In vitro and biocompatibility tests were performed on the Ultra IABP Catheter Kits. The *in vitro* tests showed that the device meets pre-determined acceptance criteria that were based on the clinical demands the device will be subjected to. The biocompatibility testing demonstrated that the Ultra IABP Catheter Kits comply with the requirements for this device classification.

h. Conclusion:

Based on the information provided in this 510(k) premarket notification, the Ultra IABP Catheter Kits are considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2009

Mr. Tom Colonna
Vice President, Regulatory Affairs & Quality Assurance
Insightra Medical
15560-C Rockfield Boulevard
Irvine, CA 92618

Re: K082746
Ultra IABP Catheter Kit, Models IMU7F-40, IMU7F-35, IMU7F-30, IMU7F-25, and IMU7F-20
Regulation Number: 21 CFR 870.3535
Regulation Name: Balloon, Intra-Aortic and Control System
Regulatory Class: Class III
Product Code: DSP
Dated: September 17, 2008
Received: September 19, 2008

Dear Mr. Colonna:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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4 Indications for Use Statement

510(k) Number (if known): K082746

Device Name: Ultra IABP Catheter Kit

Indications for Use:

The Ultra IABP is placed in the descending aorta just below the subclavian artery and is intended to improve cardiovascular function during the following situations: refractory unstable angina, impending infarction, post-infarction angina, refractory left ventricular failure, complications of acute MI (*i.e.*, acute MR or VSD or papillary muscle rapture), cardiogenic shock, support for diagnostic percutaneous revascularization and interventional procedures, ischemic related intractable ventricular arrhythmias, septic shock, interoperative 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, cardiac contusion, mechanical bridge to other assist devices and 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)

Donna R. Mahoney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082746

Page 1 of _1_

Thomas 1/8/09