K063525

Attachment D

JAN - 5 2007

510(k) SUMMARY FOR *DATASCOPE'S IABP SYSTEM FIBER OPTIC PRESSURE SENSOR INTRA-AORTIC BALLOON (IAB) CATHETER and CS300 INTRA-AORTIC BALLOON PUMP (IABP) CONTROL SYSTEM*

(Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter:	Datascope Corp. Cardiac Assist Division
Address:	15 Law Drive Fairfield, NJ 07004
Contact Person:	Nancy Cohen Manager Regulatory Affairs and Product Surveillance
Phone:	973/244-6104
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Email:	Nancy_Cohen@datascope.com
Date:	November 21, 2006

B. DEVICE INFORMATION

Generic Name:	Intra-Aortic Balloon (IAB) Catheter and Control System
Trade Name:	Datascope's IABP System [Fiber Optic Pressure Sensor Intra-Aortic Balloon (IAB) Catheter and CS300 Intra-Aortic Balloon Pump (IABP) Control System]
Classification Name:	Intra-Aortic Balloon (IAB) Catheter and Control System is classified under 21CFR 870.3535

C. PREDICATE DEVICE INFORMATION

Datascope's IABP System [Fiber Optic Pressure Sensor Intra-Aortic Balloon (IAB) Catheter and CS300 Intra-Aortic Balloon Pump (IABP) Control System] is substantially equivalent to the following marketed devices:

- K041281 - Datascope's Linear 7.5Fr. IAB, Substantially Equivalent 6/07/04
- K031636 - Datascope's CS100 IAB Pump, Substantially Equivalent 8/11/03
- K031569 - Datascope's 8Fr. IAB, Substantially Equivalent 6/10/03

- K013326 - Datascope's Fidelity 8Fr. IAB, Substantially Equivalent 11/02/01
- K060309 - Arrow AutoCAT Intra-Aortic Balloon Pump (IABP) Series, Substantially Equivalent 4/06/06
- K040801 - Arrow International's Intra-Aortic Balloon Catheter, Substantially Equivalent 5/06/04
- K021462 - Arrow International's IAB Fiber Optic Sensor (FOS)/FOS Measurement System, Substantially Equivalent 6/06/02
- K981660 Arrow International (C.R. Bard, Inc.) 8Fr 40 cc and 7Fr. 30 cc Sheathless Intra-Aortic Balloon (IAB)

D. DEVICE DESCRIPTION/INTENDED USE

DEVICE DESCRIPTION

The Datascope IABP System [Fiber Optic Pressure Sensor IAB Catheter and CS300 Intra-Aortic Balloon Pump (IABP) Control System] is used for intra-aortic balloon counterpulsation therapy in the aorta.

INTENDED USE

CS300 Intra-Aortic Balloon Pump has the following indications for use:

The 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 populations are adult and pediatric. The balloon pump is intended for use in the health care facility setting.

Datascope's Fiber Optic Pressure Sensor Intra-Aortic Balloon (IAB) Catheter has the following indications for use:

- Refractory unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. 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 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

E. TECHNOLOGICAL CHARACTERISTICS

The Datascope IABP System [Fiber Optic Pressure Sensor IAB Catheter and CS300 Intra-Aortic Balloon Pump (IABP) Control System] includes the following:

- CS300 Intra-Aortic Balloon Pump
- Fiber optic pressure Sensor IAB assembly
- Revised packaging tray with cable retention feature

These modifications to the Datascope IAB System [Fiber Optic Pressure Sensor IAB Catheter and CS300 Intra-Aortic Balloon Pump (IABP) Control System] have been demonstrated not to affect safety or effectiveness of the device.

F. NON-CLINICAL TESTS

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

G. CLINICAL TESTS

There has been no clinical evaluation of the new device in the U.S.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's IABP System [Fiber Optic Pressure Sensor IAB Catheter and CS300 Intra-Aortic Balloon Pump (IABP) Control System] is considered substantially equivalent to Datascope's currently marketed IAB Catheters and Control Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2007

Datascope Corp.
c/o Ms. Nancy Cohen
Manager Regulatory Affairs and Product Surveillance
15 Law Drive
Fairfield, NJ 07004

Re: K063525
Datascope's IABP System [Fiber Optic Pressure Sensor Intra-Aortic Balloon (IAB) Catheter and CS300 Intra-Aortic Balloon Pump (IABP) Control System]
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic Balloon and Control System
Regulatory Class: III
Product Code: DSP
Dated: December 15, 2006
Received: December 18, 2006

Dear Ms. Cohen:

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 (240) 276-0120. 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,

B Zuckerman for

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

Enclosure

- **Attachment B**

Indications for Use

510(k) Number (if known): K063525

Device Name: Datascope's IABP System Fiber Optic Pressure Sensor Intra-Aortic Balloon (IAB) Catheter & CS300 Intra-Aortic Balloon Pump (IABP) Control System)

Indications For Use:

CS300 Intra-Aortic Balloon Pump has the following indications for use:

The 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 populations are adult and pediatric. The balloon pump is intended for use in the health care facility setting.

B. Runnemo

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063525

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)

Attachment B

Indications for Use

510(k) Number (if known): K063525

Device Name: Datascope's IABP System Fiber Optic Pressure Sensor Intra-Aortic Balloon (IAB) Catheter & CS300 Intra-Aortic Balloon Pump (IABP) Control System

Indications For Use:

Datascope's Fiber Optic Pressure Sensor Intra-Aortic Balloon (IAB) Catheter has the following indications for use:

- Refractory unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. Acute MR or VSD, or papillary muscle rupture)
- Cardiogenic shock
- Support for diagnostic, percutaneous revascularization, and interventional procedures
- Ischemia related intractable ventricular arrhythmias
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- Intraoperative pulsatile flow generation
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Division of Cardiovascular Devices
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Prescription Use ___X___ AND/OR Over-The-Counter Use

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