K031636

AUG 1 1 2003

510(k) Summary of Safety and Effectiveness

Date: May 21, 2003

Submitter: Patient Monitoring Division
Datascope Corp.

Contact Person: Susan E. Mandy
Director, Clinical & Regulatory Affairs
Patient Monitoring Division
Datascope Corp.
Telephone: (201)995-8025
Fax:(201)995-8605

Device trade name: CS100 Intra-Aortic Balloon Pump

Common/usual name: Intra-aortic balloon and control system

Classification name:
21 CFR 870.3535 Intra-aortic balloon and control system

Predicate Devices: K965236 System 96 Intra-Aortic Balloon Pump
K983866 Arrow AutoCAT Intra-Aortic Balloon Pump

Device Description: The CS100 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. The CS100 is equipped with the flexibility to aid medical staff in supporting a broad range of patients. It is also designed to work in conditions which are unique to the operating room, catheterization laboratory, critical care unit and transport. The CS100 IABP has three operation modes; auto, semi auto and manual. The auto operation mode provides simplicity and minimizes operator intervention. The semi-auto and manual operation modes provide operators with flexibility for difficult clinical cases.

Intended 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.

Technology:

The CS100 Intra-Aortic Balloon Pump (IABP) is substantially equivalent to the Datascope Corp. System 96 IABP, with the exception of the auto operational mode which is equivalent to the auto operation mode of the Arrow International AutoCAT IABP, which is manufactured by Belmont Instrument Corporation. The CS100 has the same principles of operation as the S96 IABP and the Arrow International AutoCAT IABP. The CS100 IABP is differentiated from the S96 IABP by its automated operation option. The CS100 IABP also features improved ergonomics and a more intuitive user interface than the System 96 IABP.

Test Summary

The CS100 Intra-Aortic Balloon Pump complies with the voluntary standards identified in section six of this submission. Datascope's product development process required that the following activities be completed during the development of the CS100 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
- Auto Operation Mode

Conclusion

The results of all measurements demonstrated that the CS 100 Intra-Aortic Balloon Pump is as safe, as effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 2003

Datascope Corp.
Patient Monitoring Division
c/o Ms. Susan E. Mandy
Director, Clinical and Regulatory Affairs
800 MacArthur Blvd.
Mahwan, N.J. 07430

Re: K031636
CS100 Intra-Aortic Balloon Pump
Regulation Number: 21 CFR 870.3535
Regulation Name: Balloon, Intra-Aortic and Control System
Regulatory Class: Class III (three)
Product Code: DSP
Dated: May 23, 2003
Received: May 27, 2003

Dear Ms. Mandy:

This letter corrects our substantially equivalent letter of August 11, 2003 regarding the incorrect address.

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 (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); 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

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

INDICATION 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.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031636

Prescription Use Only