DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 31, 2017

Datascope Corp.
Helder Sousa
Manager, Regulatory Affairs
1300 MacArthur Blvd.
Mahwah, New Jersey 07430

Re: K163542
Trade/Device Name: CARDIOSAVE Intra-Aortic Balloon Pump
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon and Control System
Regulatory Class: Class II
Product Code: DSP
Dated: December 15, 2016
Received: December 16, 2016

Dear Helder 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

for 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): K163542

Device Name: CARDIOSAVE Intra-Aortic Balloon Pump

Indications For Use: The CARDIOSAVE Intra-Aortic Balloon Pump is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure.

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)

CARDIOSAVE INTRA-AORTIC BALLOON PUMP

510(k) Summary

Prepared in accordance with 21 CFR Part 807.92

GENERAL INFORMATION

Submitter's name and address**:** Datascope Corp.
1300 MacArthur Blvd.
Mahwah, NJ 07430

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

Phone: (973) 709-7465
Fax: (973) 629-1325
Email: helder.sousa@getinge.com
Date prepared: December 15, 2016

DEVICE INFORMATION:

Trade Name:	CARDIOSAVE Intra-Aortic Balloon Pump
Common/Generic Name:	Intra-Aortic Balloon Pump (IABP)
Classification Name:	Intra-Aortic Balloon and control system
Regulation Number:	21 CFR 870.3535
Regulatory Class:	Class II
Product Code:	DSP

PREDICATE DEVICE INFORMATION:

CARDIOSAVE Intra-Aortic Balloon Pump (K151254).

DEVICE DESCRIPTION:

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.

INDICATIONS FOR USE:
The CARDIOSAVE Intra-Aortic Balloon Pump is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATES:
The modified CARDIOSAVE Intra-Aortic Balloon Pump (IABP) is identical to the predicate CARDIOSAVE Intra-Aortic Balloon Pump (K151254) with the exception of the new CARDIOSAVE Li-Ion battery transport and storage case to be used for the CARDIOSAVE batteries for protective purposes.

PERFORMANCE DATA:
The new CARDIOSAVE Li-Ion battery transport and storage case to be used for the CARDIOSAVE Li-Ion batteries for protective purposes when not installed in the IABP complies with IEC 62133 Edition 2.0 2012-12: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

Datascope Corp. development process required that the following activities be completed during the development of the new CARDIOSAVE Li-Ion battery transport and storage case:

- Requirements specification review
- Performance testing
- Design validation

The results of the tests conducted demonstrate that the new CARDIOSAVE Li-Ion battery transport and storage case to be used for the CARDIOSAVE Li-Ion batteries when not installed in the IABP complies with IEC 62133 Edition 2.0 2012-12.

CLINICAL TESTS:
There was no clinical evaluation of the modified device.

Conclusion:
Based upon the information submitted in this Special 510(k) premarket notification, the modified device is substantially equivalent to the currently marketed CARDIOSAVE IABP. The CARDIOSAVE IABP with the new CARDIOSAVE Li-Ion battery transport and storage case is similar to the predicate device in the intended use and the fundamental scientific technology of the device. The design verification and validation testing established that the CARDIOSAVE IABP with the new CARDIOSAVE Li-Ion battery transport and storage case performs as well as the predicate device.