May 31, 2018

Datascope Corp.
Hemang Kotecha
Regulatory Affairs Specialist II
1300 MacArthur Blvd.
Mahwah, New Jersey 07430

Re: K181122
Trade/Device Name: CARDIOSAVE Intra-Aortic Balloon Pump (Hybrid Model)
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic balloon and control system
Regulatory Class: Class II
Product Code: DSP
Dated: April 27, 2018
Received: April 30, 2018

Dear Hemang Kotecha:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181122

Device Name
CARDIOSAVE IABP (Hybrid Model)

Indications for Use *(Describe)*
The CARDIOSAVE IABP (Hybrid Model) is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(K) SUMMARY

## CARDIOSAVE INTRA-AORTIC BALLOON PUMP (HYBRID MODEL)

[Prepared in accordance with 21 CFR Part 807.92]

**Submitter's Name and Address:**
Datascope Corp.
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**Contact Person for this submission:**
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**Date Prepared:** **April 27, 2018**

**Device Information:**

**Trade Name:** CARDIOSAVE IABP (Hybrid Model)

**Common/Generic Name:** Intra-Aortic Balloon Pump

**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 (K112372)

**Device Description:** The CARDIOSAVE IABP (Hybrid Model) 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 IABP (Hybrid Model) is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure.

**Intended Use:**

The CARDIOSAVE IABP (Hybrid Model) is an electromechanical system used to inflate and deflate intra-aortic balloons. The IABP 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 population is adult. The balloon pump is intended for use in the health care facility setting.

**Comparison of Technological Characteristics with the Predicate Device:**

The proposed CARDIOSAVE IABP (Hybrid Model), which is the subject of this submission, contains the same technologically characteristics as the predicate CARDIOSAVE Intra-Aortic Balloon Pump (K112372).

The proposed modification is the addition a new Top Protection Cover that shall be installed on top of the CARDIOSAVE cart.

The Top Protection Cover provides protection against liquid spills, such as saline, that may occur on top of the unit. It is

designed to remove any paths for the liquid that is spilled on top of the unit and prevent flow of the liquid into the interfacing panels, connector receptacles and air vents. Such liquid spills are hazardous as they can create bridges of resistance between the circuit components; causing the circuit not to function as intended; potentially damage the unit and possibly causing it to shut down during operation. This may impact the initiation or continuation of therapy.

**Performance Data:**

Datascope Corp. development process required that the following activities be completed during the development of the new Top Protection Cover:

- Risk Assessment
- Verification testing

The modification proposed within this submission for CARDIOSAVE IABP (Hybrid Model) does not impact the performance characteristics of the predicate device.

The results of the tests conducted demonstrate that the proposed device met its respective acceptance criteria. According to the risk assessment performed, the modification does not introduce any new risks and does not raise any new questions of safety and effectiveness.

**Clinical Tests:**

There was no clinical testing deemed necessary for the proposed device.

**Conclusion:**

Based upon the information submitted in this Special 510(k) submission, the proposed device is substantially equivalent to the currently marketed CARDIOSAVE IABP (Hybrid Model).

The CARDIOSAVE IABP (Hybrid Model) with the new Top Protection Cover is similar to the predicate device in the intended use and the fundamental scientific technology of the device. The design verification testing established that the CARDIOSAVE IABP (Hybrid Model) with the new Top Protection Cover performs same as the predicate device.