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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
DATASCOPE PERCOR STAT-DL® 9.5Fr. & 10.5 Fr.INTRA-AORTIC BALLOON (IAB)
(Prepared in accordance with 21 CFR Part 807.92)

Pursuant to Section 513(I)(3)(A) of the Food, Drug, and Cosmetic act, datascope corporation is required to submit this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Datascope Corporation chooses to submit a summary of information respecting safety and effectiveness.

A. GENERAL INFORMATION

Submitter:	Datascope Corp. Cardiac Assist Division
Address:	15 Law Drive Fairfield, NJ 07004
Contact Person:	Kevin Crossen Director, Regulatory Affairs and Quality Assurance

B. DEVICE INFORMATION

Generic Name:	Intra-Aortic Balloon (IAB)
Trade Name:	Datascope Percor STAT-DL® Intra-Aortic Balloon (IAB)
Classification Name:	Intra-Aortic Balloons (IABs) are classified under 21 CFR 870.3535
Product Code:	74DSP

C. PREDICATE DEVICE INFORMATION

Datascope's Percor STAT-DL® Intra-Aortic Balloon is substantially equivalent to the following marketed devices:

- Datascope Percor STAT-DL®9.5Fr.&10.5Fr. Intra-Aortic Balloons, K940231 & K940178.
- K905663 - Pediatric IAB
- K790775 - Datascope Type "S" IAB
- K952221- 30cc/40cc Sensation™ IAB; Model 930/940 IAB's (Boston Scientific Corp.)

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- K943919 - 9.5 Fr. Sensation™IAB (Boston Scientific Corp.)

- K961358 - 8.0 Fr. 30/40cc, 10.0 Fr. 50cc Sheathless IAB (Arrow International)

D. DEVICE DESCRIPTION/INTENDED USE

The intra-aortic balloon is placed in the descending aorta just below the subclavian artery and is intended to improve cardiovascular functioning during the following situations:

Refractory ventricular failure
Cardiogenic shock
Unstable refractory angina
Impending infarction
Mechanical complications due to acute myocardial infarction
Ischemic related intractable ventricular arrhythmias
Cardiac support for high risk surgical patients and coronary angiography or angioplasty patients
Septic shock
Weaning from cardiopulmonary bypass
Interoperative pulsatile flow generation
Support for failed angioplasty and valvuloplasty

E. TECHNOLOGICAL CHARACTERISTICS

Datascope's Percor STAT-DL® 9.5Fr. & 10.5Fr. IAB are identical to the predicate devices with regard to its indications for use and dimensional specifications. They differ technologically respecting material grade and chemical composition of the components. The difference in material grade and chemical composition has been demonstrated not to affect safety or efficacy 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.

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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 Percor STAT-DL® 9.5Fr. & 10.5Fr. IABs are considered substantially equivalent to Datascope's currently marketed IABs.