



K960166

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Datascope[®]
Cardiac Assist Division

K960166

**SUMMARY OF SAFETY AND EFFECTIVENESS
FOR**

***DATASCOPE PERCOR STAT-DL[®] 9.5Fr. INTRA-AORTIC BALLOON (IAB)
WITH
ALTERNATE INNER LUMEN MATERIAL***

(Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter: Datascope Corp
Address: 15 Law Drive
Fairfield, NJ 07004
Contact Person: Diane DePonte Arpino

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

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. Intra-Aortic Balloon,
K905056 & K940178.

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 angina	Unstable refractory angina
Impending infarction	Septic shock
Cardiac support for high risk surgical patients	
Ischemic related intractable ventricular arrhythmias	
Mechanical complications due to acute myocardial infarction	

E. TECHNOLOGICAL CHARACTERISTICS

Datascope's Percor STAT-DL® 9.5Fr. IAB is identical to the predicate device with regard to its indications for use and dimensional specifications. It differs technologically respecting material grade and chemical composition of the inner lumen. 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.

G. CLINICAL TESTS

There has been no clinical evaluation of the new device.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's Percor STAT-DL® 9.5Fr. IAB is considered substantially equivalent to Datascope's currently marketed IAB.