

K994157

MAR 13 2000

**10(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**FOR**

***DATASCOPE 8Fr. Polyimide***

***25, 34 & 40cc Intra-Aortic Balloon Catheters***

(Prepared in accordance with 21 CFR Part 807.92)

Pursuant to Section 513(I)(3)(A) of the Food, Drug, and Cosmetic act, Datascope Corp. 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 Corp. 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: Whitney G. Törning  
Director, Regulatory Affairs & Product Surveillance

**B. DEVICE INFORMATION**

Generic Name: Intra-Aortic Balloon (IAB)  
Trade Name: Datascope 8Fr. 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:

K980385 - 8Fr. Co-Lumen (CL) Intra-Aortic Balloon 34cc and 40cc (IAB) & Accessories

K980780- Percor-STAT-DL 9.5 Fr. 25cc, 34cc and 40cc Intra-Aortic Balloon (IAB) Catheter with Alternate "B" Membrane for Optional Sheathless Insertion.

#### **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 8Fr. Polyimide 25, 34 & 40cc IAB is substantially equivalent to the predicate devices with regard to its indications for use. 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.

#### **G. CLINICAL TESTS**

There have been no clinical evaluations of the new device.

#### **H. CONCLUSIONS**

Based on the information presented in this 510(k) premarket notification, Datascope's 8Fr. Polyimide IAB is considered substantially equivalent to Datascope's currently marketed IABs.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 13 2000

Ms. Whitney Törning  
Datascope Corporation  
Cardiac Assist Division  
15 Law Drive, CN 40011  
Fairfield, NJ 07004

Re: K994157  
Datascope's 8FR. Polymide 25 cc, 34 cc and 40 cc Intra-Aortic  
Balloon Catheters  
Regulatory Class: III (three)  
Product Code: 74DSP  
Dated: November 29, 1999  
Received: December 9, 1999

Dear Ms. Törning:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

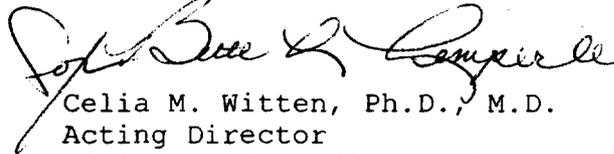
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

Page 2 - Ms. Whitney Törning

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations. This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K994157

Device Name: Datascope's 8Fr. Polyimide 25, 34 & 40cc Intra-Aortic Balloon Catheters

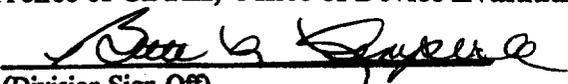
**Indications for Use:**

1. Refractory ventricular failure.
2. Cardiogenic shock.
3. Unstable refractory angina.
4. Impending infarction.
5. Mechanical complications due to acute myocardial infarction, i.e., ventricular septal defect, mitral regurgitation or papillary muscle rupture.
6. Ischemia related intractable ventricular arrhythmias.
7. Cardiac support for high risk general surgical patients and coronary angiography/angioplasty patients.
8. Septic shock.
9. Weaning from cardiopulmonary bypass.
10. Intraoperative pulsatile flow generation.
11. Support for failed angioplasty and valvuloplasty.

This information can be found in Volume 1 (Section 3 - Attachment II) of our Premarket Notification under the section titled "II. Indications".

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 994157