K020257

APR 24 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

DATASCOPE Intra-Aortic Balloon Catheter Systems

(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:	JoAnn Wolf Regulatory Affairs Associate

B. DEVICE INFORMATION

Generic Name: Intra-Aortic Balloon (IAB) Catheter

Trade Name: Datascope Intra-Aortic Balloon (IAB) Catheter

Classification Name: Intra-Aortic Balloon (IAB) Catheters are classified under 21 CFR 870.3535

Product Code: 74DSP

C. PREDICATE DEVICE INFORMATION

Datascope's Intra-Aortic Balloon Catheters Indications for Use are substantially equivalent to the following marketed devices:

K013326 -	Datascope 8Fr. 25, 34 & 40cc Alt B IAB
K003598 -	Datascope Profile 8Fr. 34 & 40cc Alt B IAB
K980780 -	Datascope Percor STAT-DL 9.5Fr. 25, 34 & 40cc Alt B IAB
K964987 -	Percor STAT-DL 9.5Fr. 25 & 40cc IABs for Optional Sheathless Insertion and Percor STAT-DL 10.5Fr. 40 & 50cc IABs for Sheath Insertion
K965236 -	Datascope System 96 Intra-Aortic Balloon Pump
K002256 -	Arrow ACAT 2 Intra-Aortic Balloon Pump

All of the above referenced premarket notifications were found substantially equivalent by FDA.

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 unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. Acute MR or VSD, or papillary muscle rupture)
- Cardiogenic shock
- Support for diagnostic, percutaneous revascularization, and interventional procedures.
- Ischemia related intractable ventricular arrhythmias
- Septic shock
- Intraoperative pulsatile flow generation
- Weaning from bypass
- Cardiac support for non-cardiac surgery
- Prophylactic support in preparation for cardiac surgery
- Post surgical myocardial dysfunction/low cardiac output syndrome
- Myocardial contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects

E. TECHNOLOGICAL CHARACTERISTICS

Datascope's enhanced Indications for Use for IAB Systems are substantially equivalent to the predicate devices.

Supporting published data establish that the expanded Indications for Use is substantially equivalent to the predicate devices and does not affect the safety and effectiveness of the device.

F. NON-CLINICAL TESTS

N/A

G. CLINICAL TESTS

N/A

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's expanded Indications for Use for the IAB Catheter System are considered substantially equivalent to the predicate devices' Indications for Use for their currently marketed IAB Catheter System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2002

Ms. JoAnn Wolf
Regulatory Affairs Associate
Datascope Corporation
Cardiac Assist Division
15 Law Drive
Fairfield, NJ 07004

Re: K020257
Trade Name: Datascope's 8Fr. 25, 34 & 40cc IAB; True Sheathless DL 9.5Fr. 25, 34 & 40cc IAB; Percor STAT-DL 9.5Fr. 34 & 40cc IAB for Optional Sheathless Insertion; Percor STAT-DL 10.5Fr. 50cc IAB
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon Catheter
Regulatory Class: Class III (three)
Product Code: DSP
Dated: January 23, 2002
Received: January 24, 2002

Dear Ms. Wolf:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna-Bea Tillman, Ph.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): K020257

Device Name: Datascope's 8Fr. 25, 34 & 40cc IAB; True Sheathless DL 9.5Fr., 25, 34 & 40cc IAB; Percor STAT-DL 9.5Fr. 34 & 40cc IAB for Optional Sheathless Insertion; Percor STAT-DL 10.5Fr. 50cc IAB

Indications for Use:

Intra-Aortic Balloon Catheter System to be used for the following:

- Refractory unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. Acute MR or VSD, or papillary muscle rupture)
- Cardiogenic shock
- Support for diagnostic, percutaneous revascularization, and interventional procedures.
- Ischemia related intractable ventricular arrhythmias
- Septic shock
- Intraoperative pulsatile flow generation
- Weaning from bypass
- Cardiac support for non-cardiac surgery
- Prophylactic support in preparation for cardiac surgery
- Post surgical myocardial dysfunction/low cardiac output syndrome
- Myocardial contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects

This information can be found in Section 3 - Attachment I 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)

Prescription Use X **OR** **Over-the-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020257