K980385

MAY 1 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
DATASCOPE 8Fr. CO-LUMEN (CL)
INTRA-AORTIC BALLOON (IAB) & ACCESSORIES

(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 Torning Manager, Regulatory Affairs and Product Surveillance

B. DEVICE INFORMATION

Generic Names:	Intra-Aortic Balloon (IAB), Catheter Introducer, Catheter guide wire
Trade Names:	Datascope 8Fr. Co-Lumen (CL) Intra-Aortic Balloon (IAB) and kit accessories (catheter introducer, catheter guide wire)
Classification Names:	Intra-Aortic Balloons (IABs) are classified under 21 CFR 870.3535, Catheter Introducers are classified under 21 CFR 870.1340, and Catheter Guide Wires are classified under 21 CFR 870.1330.
Product Codes:	74DSP, 74DYB, and 74DQX respectively.

C. PREDICATE DEVICE INFORMATION

Datascope's 8Fr. Co-Lumen 34 & 40cc IABs for Optional Sheathless Insertion are substantially equivalent to the devices as described in:

1) K790775 - Datascope Type "S" IAB.

2) K905056 - Datascope Percor STAT-DL 9.5Fr. IAB with Optional Insertion without an Introducer Sheath.

3) K910997B - Datascope Percor STAT Intra Aortic Balloons with Alternate Coating.

4) K911000 - Datascope Percor STAT Co-Lumen 8.5Fr. 40cc IABs.

5) K914802 - Datascope Percor STAT-DL 9.5Fr. 34cc IAB Sheathless Insertion.

6) K940178 - Datascope Percor STAT-DL 9.5Fr. 34cc & 40cc IABs with an alternate inner lumen of 80/20 hard/soft Estane

7) K940231- Datascope Percor STAT-DL 9.5Fr. 40cc IAB with an alternate membrane material; a Polyurethane/Silicone blend.

8) K960166 - Datascope Percor STAT-DL 9.5Fr. 34 & 40cc IABs for Optional Sheathless Insertion with Alternate Inner Lumen Material (Texin).

9) K960713 - Arrow International 8Fr. 40cc NarrowFlex™ IAB (nitinol inner lumen)
K961358 - Arrow International 8Fr. 40cc NarrowFlex™ IAB for sheathless insertion (nitinol inner lumen)

11) K963865 - Arrow International 8Fr. 30cc NarrowFlex™ IAB (nitinol inner lumen)
K961358 - Arrow International 8Fr.30cc NarrowFlex™ IAB for sheathless insertion nitinol inner lumen)

12) 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 with Alternate Inner Lumen Material (80/20 hard/soft Estane) & Alternate Membrane Material (Polyurethane/Silicone) blend.

13) K972113 - Boston Scientific Corp. Sub-9 Nitinol 30cc and 40cc IAB for Sheathless Insertion (nitinol inner lumen)

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

An insertion kit containing a catheter introducer, composed of an 8 Fr. catheter introducer sheath with integrated hemovalve and dilator, a stepped vessel dilator, and a guide wire (.020") use the same materials as previously cleared 510(k)'s.

Datascope's 8Fr. Catheter Introducer and Stepped Vessel Dilator for use with the insertion of the 8Fr. IAB is substantially equivalent to the devices as described in:

1) K820834 - Datascope's 10Fr. Percor Percutaneous Introducer with Hemostasis Valve

2) K902674 - Datascope's Arterial Cannula with Access Port

3) K904476 - Datascope's 5 to 9 Fr. Stepped Vessel Dilator

4) K904477 - Datascope's Stiff Guidewire for use with Datascope IABs

5) K924607 - Arrow Fischell Corp.'s Super Arrow-Flex Percutaneous Sheath Introducer

6) K943896 - Datascope's Staged Guide Wire for use with Datascope Percor STAT-DL IABs

7) K955785 - C.R. Bard's TS and Input Percutaneous Arterial/Venous Catheter Introducer Set

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

Datascope's .020" guidewire for use with the insertion of the 8Fr. IAB is substantially equivalent to the devices as described in:

1) K904477 - Datascope's Stiff Guidewire for use with Datascope IABs

2) K943896 - Datascope's Staged Guide Wire for use with Datascope Percor STAT-DL IABs

3) K952430 - Flexmedic's Finesse guide wire for coronary use

4) K960563 - Scimed Sceptor ™ PTCA guide wire (platinum spring coil)

5) K961445 - Terumo's Radiofocus® Glidewire® for coronary use (nickel titanium coil with platinum spring coil)

6) K970994 - Lake Region's Nitinol core and platinum coil .014" - .045"guide wire for extravascular use.

7) K971322 - Lake Region's Nitinol core and platinum coil .014" and .018" guide wire for intravascular use.

All of the above referenced premarket notifications were found substantially equivalent by FDA with the exception of K971322 which is currently pending FDA's SE decision.

Datascope's Devices described above are referenced in this Premarket Notification as predicate devices for the 8 Fr. IAB insertion kit, and catheter introducer set, and guidewire pack. All other device components that make up the insertion kit are the same as previously cleared by the 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 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. Co-Lumen IABs with accessories are substantially equivalent to the predicate devices with regard to its indications for use. They differ technologically respecting material composition and dimensional specifications of the components. The difference in material composition and dimensional specifications have 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

The 8Fr. Co-Lumen 34cc and 40cc Intra-Aortic Balloon Catheter with accessories are CE Marked and commercially available in Europe.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's 8Fr. Co-Lumen IABs with accessories are considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

Ms. Whitney G. Törning
Manager, Regulatory Affairs &
Product Surveillance
Datascope Corporation
Cardiac Assist Division
15 Law Drive, CN 40011
Fairfield, NJ 07004

Re: K980385
Datascope 8Fr. CO-LUMEN (CL) Intra-Aortic Balloon
34cc and 40cc (IAB) & Accessories
Regulatory Class: III (Three)
Product Code: DSP
Dated: January 28, 1998
Received: February 2, 1998

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 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 (Premarket 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 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" (21 CFR 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/dsmamain.html."

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980385

Device Name: Datascope's 8Fr. Co-Lumen 34 & 40cc Intra-Aortic Balloon Catheters for Optional Sheathless Insertion with Accessories.

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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980385