

D

K973007

NOV - 6 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS
FOR**

DATASCOPE'S 10 Fr. FLEXISHEATH™ PERCUTANEOUS INTRODUCER

(Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter: Datascope Corp.
Cardiac Assist Division
Address: 15 Law Drive
Fairfield, NJ 07004
Contact Person: Whitney Torning
Supervisor, Regulatory Affairs

B. DEVICE INFORMATION

Generic Name: Catheter Introducer
Trade Name: Datascope's FlexiSheath Percutaneous Introducer
Classification Name: Introducer, Catheters are classified under
21 CFR 870.1340

C. PREDICATE DEVICE INFORMATION

Datascope's FlexiSheath Percutaneous Introducer is substantially equivalent to the following marketed devices:

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

K902674 - Datascope's Arterial cannula with Access Port

K924607 - Super Arrow-Flex Percutaneous Sheath Introducer (Arrow Fischell Corp.)

K940092 - Bard's Input Percutaneous Arterial/Venous Catheter Introducer



K940178 - Datascope's Percor STAT-DL 9.5 Fr. 34cc and 40cc & 10.5 Fr. 40cc and 50cc IABs with Alternate Inner Lumen

K940231 - Datascope's Percor STAT-DL 40cc IAB with Alternate Membrane Material

K943896 - Datascope's Staged Guide Wire for use with Datascope's Percor STAT-IABs.

K964987 - Datascope's Percor STAT-DL 9.5 Fr. 25 and 40cc IAB.

D. DEVICE DESCRIPTION/INTENDED USE

Datascope's 10 Fr. FlexiSheath™ Percutaneous Introducer is intended for the percutaneous introduction of Datascope's 9.5 Fr. Intra-Aortic Balloon Catheters.

E. TECHNOLOGICAL CHARACTERISTICS

The difference in material grade and chemical composition has been demonstrated not to effect 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 in the U.S.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's 10 Fr. FlexiSheath percutaneous introducer is considered substantially equivalent to Datascope's currently marketed catheter introducer.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Whitney Torning
Supervisor, Regulatory Affairs
Datascope Corporation
Cardiac Assist Division
15 Law Drive
CN 40011
Fairfield, New Jersey 07004

NOV - 6 1997

Re: K973007
10 Fr. Flexisheath™ Percutaneous Introducer
Regulatory Class: II (Two)
Product Code: DYB
Dated: August 11, 1997
Received: August 13, 1997

Dear Ms. Torning:

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.

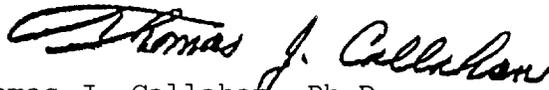
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Whitney Torning

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

Enclosure

870, 1340 - DVB II - Catheter Introducer

510(k) Number (if known): K973007

Device Name: Datascope's 10 Fr. FlexiSheath™ Percutaneous Introducer

Indications for Use:

Datascope's 10 Fr. FlexiSheath™ Percutaneous Introducer is intended for the percutaneous introduction of Datascope's 9.5Fr. Intra-Aortic Balloon Catheters.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973007

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)