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510(k) SUMMARY

SEP 2 3 2004

A. **Submitter Information:**

Submitter:	Datascope Interventional Products Division 1300 MacArthur Blvd. Mahwah, NJ 07430-0605 Phone: (201) 995-8700 Fax: (201) 995-8992
Contact:	Patrice Napoda Manager, Regulatory Affairs
Date Prepared:	July 26, 2004

B. **Trade Name:** Datascope Chronic Dialysis Catheter
Common Name: Hemodialysis Catheter, Implanted
Classification: 78 MSD
C.F.R. Section: 876.5540

C. **Predicate Device:** K994105 Medcomp Hemo-Flow™ Catheter

D. **Device Description:**

The Datascope Chronic Dialysis Catheter is double lumen polyurethane catheter (Carbothane) that provides two dedicated (arterial/venous) access lumens. Both lumens are "D" shaped, open at the distal tip, with and without side holes. Each lumen is connected through an extension line with female luer connectors. The transition between lumen and extension is housed within a molded hub.

Product Features: The catheter lumen is composed of a soft, thermo sensitive, polyurethane material that is rigid upon insertion and once it reaches body temperature it becomes soft to reduce vessel trauma. The catheter assembly contains a pre-loaded stylet for ease of insertion. The Datascope Chronic Dialysis Catheter has a unique "over the wire" design that eliminates the need for a tear-away sheath during catheter insertion.

The catheter hub is molded from soft, pliable polyurethane to increase patient comfort.

The dialysis extensions are color coded with a red luer and a clamp for the arterial lumen, a blue luer and a clamp for the venous lumen for easy identification.

Physical Dimensions:
Lumen Outer Diameter: 14.5 French

Lumen Length:
Straight 24, 28, 32, 36 & 40cm

Lumen Dimensions: Outer Diameter 0.193 +/- .003
Inner Diameter 0.122 +.002/-.003

Lumen Side Holes: With and Without

E. **Intended Use:**

The Datascope Chronic Dialysis Catheter is indicated for use in attaining long-term access for hemodialysis and apheresis. It may be implanted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include the subclavian vein as required.

F. **Comparison to Predicate Device:**

The technological characteristics of the Datascope Chronic Dialysis Catheter are substantially equivalent to the predicate device in terms of intended use, insertion method, design, materials, performance, labeling, manufacturing process, and method of sterilization.

The modifications include:

- Pre-Loaded stylet
- Without side hole design
- Slightly different hub design
- Different tip design
- Rotating suture wing

G. **Performance Data:**

In vitro performance data for the Datascope Chronic Dialysis Catheter includes force @ break, air/liquid leak, recirculation, flow vs. pressure, and gravity flow, all demonstrate that this device is substantially equivalent to the legally marketed predicate device.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2004

Ms. Patrice Napoda
Manager, Regulatory Affairs
Datascope Corporation
Interventional Products Division
1300 MacArthur Blvd.
MAHWAH NJ 07430-0605

Re: K042016
Trade/Device Name: Datascope ProGuide Chronic Hemodialysis Catheter, with accessories; Models 61124, -28, -32, -36, and -40, With Side Holes; and, Models 62124, -28, -32, -36, and -40, Without Side Holes
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: July 26, 2004
Received: July 27, 2004

Dear Ms. Napoda:

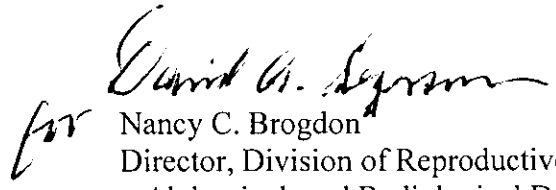
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number:

Device Name: DATASCOPE PROGUIDE CHRONIC DIALYSIS CATHETER

Indications for use:

The Datascope Chronic Dialysis catheter is indicated for use in attaining long-term access for hemodialysis and apheresis.

It may be implanted percutaneously and is primarily placed in the internal jugular vein of an adult patient.

Alternate insertion sites include the subclavian vein as required.

(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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K042016

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

(Optional Format 1-2-96)