



K 983830

Mallinckrodt Inc.
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510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted as required by SMDA of 1990.

Date: March 17, 1999

Applicant: Mallinckrodt Inc.
Address: 675 McDonnell Blvd.
PO Box 5840
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Owner/Operator No: 1925021
Contact Person: Teresa O'Shea
Title: Regulatory Affairs Associate
Telephone: (314) 654-3944
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a. Trade Name: 4 Fr. = Finch
5 Fr. = Copperhead

b. Common Name: Peripheral Percutaneous Transluminal Angioplasty Catheter

c. Classification of Device: Surgical Vessel Dilator
CV (74) LIT
Class II (performance standards)
21 CFR 870.4475

d. Identification of Predicate Device(s):	<u>510(k) #</u>
Advanced Cardiovascular (ACS) Vantage Dilatation Catheter	K965183
Bard Tru-Trac Peripheral Balloon Dilatation Catheter	K960517
MediTech Ultra-Thin Balloon Dilatation Catheter	K924320
Peripheral Systems (PSG) Advance 418 Dilatation Catheter	K904984
MediTech Symmetry Balloon Dilatation Catheter	K953602
MediTech Sub-4 Balloon Dilatation Catheter	K924047

e. Intended use:
The Mallinckrodt Peripheral Dilatation Catheter is intended for use in Percutaneous Transluminal Angioplasty (PTA) of the peripheral vasculature system, such as the renal, iliac, femoral, popliteal, peroneal, and profunda arteries.

a. Device Description:

The Mallinckrodt PTA Catheter is intended for single patient use and is disposable, sterile and non-pyrogenic. This dilatation catheter is a coaxial double lumen catheter with a balloon mounted near the distal tip. The balloon is designed to inflate to a known diameter and length at pressures stated on the label (nominal inflation). The outer lumen is used for inflation of the balloon while the inner lumen permits (1) the use of a guide wire to facilitate catheter advancement to and through the stenosis to be dilated, and (2) low flow administration of contrast media to aid in correct positioning of the balloon. The lumens bifurcate from the catheter shaft to two molded hubs (proximal end of catheter), one for the inflation lumen and one for the guide wire lumen. The hubs are labeled for easy identification. The bifurcation is supported by a strain relief sleeve at the catheter end. Two radiopaque markers, within the balloon segment of the catheter, delineate the working length of the balloon for proper balloon orientation within a stenosis. The catheter tip is a highly radiopaque, soft, atraumatic material.

The Mallinckrodt PTA Catheter is available in two shaft diameters (4 and 5 Fr) and several shaft lengths (4 Fr - 90, 135 cm and 5 Fr - 45, 75, 125 cm). The catheter has a range of balloon sizes from 3 mm to 12 mm in inflated diameter and from 2 to 10 cm in length. (Note: Neither the 4 nor 5 Fr catheter with 12 mm balloon is available in 8 and 10 cm length.) The catheters will be available with or without a hydrophilic coating.

g. Technological Characteristics and Rationale for Substantial Equivalence:

The Mallinckrodt PTA Catheter is substantially equivalent to the predicate devices listed above in terms of intended use, functionality, performance and safety. All of the predicate devices listed have been found to be substantially equivalent to devices which were in commercial distribution prior to May 28, 1976.

The Mallinckrodt PTA Catheter is inserted percutaneously, generally through an introducer and over a guidewire. The catheter is advanced within the vessel to the point of lesion and inflated with fluid to a recommended pressure and known diameter for dilatation of the vessel.

The Mallinckrodt PTA Catheter is constructed of biocompatible materials. The shaft is constructed of Nylon. The balloon is constructed of PET (polyethyleneterephthalate), the marker bands are platinum.

h. Safety and Performance Studies:

There are no significant changes to the Mallinckrodt PTA catheter from the predicate device(s) which could affect safety, effectiveness or intended use. Bench testing was conducted for the following characteristics:

- balloon minimum burst strength
- balloon distensibility
- balloon inflation/deflation performance
- balloon fatigue (repeat balloon inflation)
- bond strength
- catheter diameter and balloon profile
- over-the-arch torque strength
- over-the-arch torque response
- balloon preparation
- catheter body burst testing
- contrast medium flow rate

The results of each test were found to be acceptable.

Finished PTA Catheters including both 4 and 5 Fr catheters with hydrophilic coating were tested, in accordance with ISO 10993 for the following biocompatibility tests:

- Sensitization Assay
- Irritation Tests
- Cytotoxicity
- Systemic Toxicity (acute)
- Hemocompatibility (Thromboresistance, C3a Complement Activation, Plasma Recalcification)
- Hemolysis
- Pyrogenicity
- Implantation Tests

The results of each test were found to be acceptable.

g. Conclusions:

Based upon the indications for use, technological characteristics, and safety and performance studies, the Mallinckrodt PTA Catheter has been shown to be safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1999

Ms. Teresa O'Shea
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675 McDonnell Blvd.
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St. Louis, MO 63134

Re: K983830
Trade Name: Finch (4 Fr.) and Copperhead (5 Fr.) Percutaneous
Transluminal Angioplasty (PTA) Catheters
Regulatory Class: II
Product Code: LIT
Dated: February 26, 1999
Received: February 26, 1999

Dear Ms. O'Shea:

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,

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) 594-4586. 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,



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

Enclosure

