K022738

SEP 13 2002

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Guidant Corporation Endovascular Solutions
Submitter's Address:	1525 O'Brien Drive Menlo Park, CA 94025
Telephone: **Fax**:	(650) 617-5218 (650) 617-5024
Contact Person:	Nadine Sakakini
Date Prepared:	August 16, 2002
Device Trade Name:	AGILTRAC™ .035 Peripheral Dilatation Catheter
Device Common Name:	Percutaneous Transluminal Angioplasty Catheter
Device Classification Name:	DQY
Device Classification:	Class II

Summary of Substantial Equivalence:

The AGILTRAC™ .035 Peripheral Dilatation Catheter is available with balloon diameters of 4.0-10.0 mm, with lengths of 20, 40 and 60 mm, 12.0 and 14.0 mm balloon diameters with lengths of 20 and 40 mm, 4.0-8.0 mm balloon diameters with a length of 80mm and 4.0-7.0 mm balloon diameters with a length of 100mm. The catheter lengths are 55 cm, 80 cm and 135 cm. The AGILTRAC™ .035 Peripheral Dilatation Catheter is substantially equivalent to Guidant's AGILTRAC™ .018 Peripheral Dilatation Catheter consisting of balloon diameters of 4.0-12.0mm, balloon lengths of 20, 30, 40 and 60 mm with system lengths of 80cm and 135 cm. The AGILTRAC™ .035 Peripheral Dilatation Catheter is substantially equivalent to the legally marketed comparison device with respect to design, materials, method of delivery and intended use.

Device Description:

The AGILTRAC™ .035 Peripheral Dilatation Catheter is an over the wire catheter with an XCELON™ (nylon blend) balloon bonded at the distal end. The shaft is a dual lumen design. The smaller lumen provides for inflation of the balloon with contrast medium and the larger lumen permits use of a 0.035" guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The distal 20 cm of the catheter shaft and the entire length of the balloon are coated with Microglide®, a silicone based material used to reduce friction by providing a surface film over the catheter shaft.

The balloon, which has two (2) radiopaque markers to aid in positioning the balloon in the stenosis, is designed to provide an expandable segment of known diameter and length at specific pressures.

The proximal end of the catheter has a sidearm adaptor that provides access to the inflation lumen and guidewire lumen. It is designed with a luer-lock fitting for connection with an inflation device.

Indications for Use:

The AGILTRAC™ .035 Peripheral Dilatation Catheter is intended:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries); and
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics:

Comparisons of the subject and predicate device show that technological characteristics such as materials, biocompatibility, mode of operation, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate device, the AGILTRAC™ .018 Peripheral Dilatation Catheter.

Performance Data:

The safety and effectiveness of the AGILTRAC™ .035 Peripheral Dilatation Catheter has been demonstrated through data collected from *in vitro* bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Guidant Corporation
c/o Ms. Nadine Sakakini
Regulatory Affairs Associate
1525 O'Brian Drive
Menlo Park, CA 94025

Re: K022738
Trade Name: AGILTRAC™ .035 Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 16, 2002
Received: August 19, 2002

Dear Ms. Sakakini:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K022738

Device Name: AGILTRAC™ .035 Peripheral Dilatation Catheter

Indications for Use:

The AGILTRAC™ .035 Peripheral Dilatation Catheter is indicated for the dilatation of stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022738