

1023320

DEC 1 0 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: (650) 470-6372
Fax: (650) 617-5024

Contact Person: Michelle Grossman

Date Prepared: October 2, 2002

Device Trade Name: AGILTRAC™ .035 Peripheral Dilatation Catheter

Device Common Name: Balloon Catheter

Device Classification Name: LIT

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 Ancure® Iliac Balloon Catheter consisting of balloon diameters of 9.5 – 14.5 in 1 mm increments, balloon lengths of 30 mm with system. 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 dual lumen tubing 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 dual lumen tubing.

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 secure attachment systems in the iliac arteries and/or
- To expand vascular prosthesis limbs.

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, Ancure® Iliac Balloon 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2002

Guidant Corporation
c/o Ms. Michelle Grossman
1525 O'Brien Drive
Menlo Park, CA 94025

Re: K023320
Guidant Aqiltrac .035 Peripheral Dilatation Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY and LIT
Dated: October 2, 2002
Received: October 4, 2002

Dear Ms. Grossman:

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

Page 2 – Ms. Michelle Grossman

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), 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

510(k) Number (if known): K023320

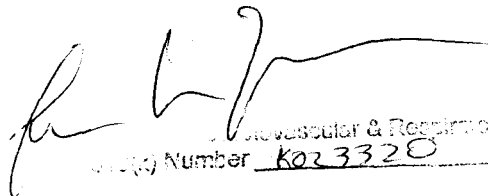
Device Name: Guidant Agiltrac .035 Peripheral Dilatation Catheter

Indications For Use: The AGILTRAC™ .035 Periheral Dilatation Catheter is intended to:

- dilate stenoses in peripheral arteries
- treat obstructive lesions of native or synthetic A-V fistulae
- secure the attachment systems in the iliac arteries, and
- to expand vascular prosthesis limbs

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


Vascular & Respiratory Devices
510(k) Number K023320

(Optional Format 3-10-98)