GUIDANT

510(k) SUMMARY

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

Submitter's Name:	Guidant Corporation
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95052
Telephone: **Fax:**	408-845-2233 408-845-2304
Contact Person:	Virginia Singer
Date Prepared:	October 20, 2004
Device Trade Name:	RX ACCUNET™ 2 Embolic Protection System
Device Common Name:	Embolic Protection System
Device Classification Name:	Embolic Protection System
Device Classification:	Class II

Summary of Substantial Equivalence:

The RX ACCUNET™ 2 Embolic Protection System is substantially equivalent to the RX ACCUNET™ Embolic Protection System.

Device Description:

The RX ACCUNET™ 2 Embolic Protection System is a filtration type embolic protection device, filtering distal to the interventional site. The System consists of the RX ACCUNET™ Delivery System and a second-generation RX ACCUNET™ 2 Recovery Catheter. The RX ACCUNET™ 2 Embolic Protection System is delivered via a Delivery Sheath with a flexible tip coil that facilitates movement of the Sheath through tortuous anatomy. Once across the lesion, the Filter Basket is expanded in the arterial lumen by peeling the Delivery Sheath from the guide wire using the torque device and peel away adapter. At the conclusion of the interventional procedure, the Filter Basket is collapsed inside the Recovery Catheter. Once collapsed, the entire system is removed as a single unit. The Recovery Catheter has a radiopaque tip to facilitate movement though tortuous anatomy

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Intended Use:

The RX ACCUNET™ 2 Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.25 mm and 7.0 mm.

Technological Characteristics:

The design modifications incorporated into the RX ACCUNET™ 2 Embolic Protection System include minor material, dimensional and design configuration changes made to the RX ACCUNET™ 2 Recovery System. No changes were made to the RX ACCUNET™ Delivery System.

The RX ACCUNET™ 2 Embolic Protection System is substantially equivalent to the RX ACCUNET™ Embolic Protection Systems (K024418) with regard to device design, principals of operation, materials, and indications for use. The following design attributes are the same or similar for both subject devices and the predicate device:

- Rapid exchange systems
- Filter based technology
- Polyurethane filter membrane
- Nitinol filter/basket component
- Compatibility with .014" guidewires
- Compatibility with 6F guide catheters
- Available in 190 and/or 300 cm lengths
- Accommodates same vessel sizes
- Radiopaque guidewire tips and/or delivery sheath tips
- Radiopaque markers on filter

Any new issues of safety or efficacy were addressed through pre-clinical evaluation including functional, *in vivo* and *in vitro* testing.

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate devices.

Performance Data:

The results of the *in vitro* bench tests and *in vivo* studies demonstrated the safety and effectiveness of the RX ACCUNET™ 2 Embolic Protection System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2004

Ms. Virginia Singer
Manager Regulatory Affairs
Guidant Corporation
Mailstop S216
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K042908
RX ACCUNET™ 2 Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NFA
Dated: October 20, 2004
Received: October 21, 2004

Dear Ms. Singer:

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), please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Donna R. Bachner

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: K042908

Device Name: RX ACCUNET™ 2 Embolic Protection System

Indications For Use: The RX ACCUNET™ Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.25 mm and 7.0 mm.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochniak

(Division Sign-Off)
Division of Cardiovascular Devices

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