

510(k) SUMMARY

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

1. Submitter's Name: Guidant Corporation
 Advanced Cardiovascular Systems, Inc.
 Submitter's Address: 3200 Lakeside Drive
 Santa Clara, CA 95054
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 Contact Person: Susan Silavin, Ph.D.
 Date Prepared: August 28, 1998

2. Device Trade Name: RX VIATRAC™ 14 Peripheral Dilatation Catheter

 Device Common Name: Percutaneous Transluminal Angioplasty Catheter

 Device Classification Name: LIT

3. Predicate Devices: Cordis Jupiter™ PTA Catheter (K970299)
 Cordis OPTA 5™ PTA Catheter (K972825)

4. Device Description:

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is a rapid exchange catheter with an integrated shaft system and an XCELON™ (nylon blend) balloon bonded at the distal end. The shaft has a combination of a single lumen design at the proximal end and a coaxial lumen at the distal end. The proximal lumen provides for inflation of the balloon with contrast medium. The distal lumen permits use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The proximal shaft has a tapered stainless steel mandrel which provides support and flexibility to the shaft and is attached at the proximal end.

The balloon, which has 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 single arm adaptor that provides access to the inflation lumen. It is designed with a luer-lock fitting for connection with an inflation device.

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is available in 75 cm and 135 cm catheter lengths and with balloon diameters of 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 and 7.0 mm.

5. Intended Use:

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated for dilatation of stenoses in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, the RX VIATRAC 14 Peripheral Dilatation Catheter is indicated for balloon dilatation of the PALMAZ™ P204 stent following implantation. It is not intended for use in the coronary vasculature.

6. Technological Characteristics:

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

7. Performance Data:

Bench testing was performed to demonstrate that the met the acceptance criteria and performed similar to the predicate Cordis Jupiter™ and OPTA 5™ PTA Catheters. The following tests were performed:

Accelerated Aging Testing
Catheter Preparation Test
Crossing Profile/Collapsed Profile
Balloon Compliance Test
Balloon Inflation/Deflation Times
Balloon Fatigue Test
Balloon Rupture Test
Catheter Soft Tip Tensile Test
Catheter Tensile Test
Catheter Bend Integrity Test
Catheter Shaft Pressure Test
Inner Member Collapse Test
Catheter Wall/Mandrel Penetration Test
Support Mandrel Pull Test
In-Stent Balloon Rupture Test
In-Stent Balloon Fatigue Test

The results from the bench tests showed that the new RX VIATRAC™ 14 Peripheral Dilatation Catheter met acceptance criteria and performed in a manner equivalent to the predicate Cordis Jupiter™ and Cordis OPTA 5™ PTA Catheters. No new safety or effectiveness issues were raised during the testing program.

8. Conclusions:

Since the new RX VIATRAC™ 14 Peripheral Dilatation Catheter has the same intended use, similar design and technological characteristics, equivalent performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the RX VIATRAC™ 14 Peripheral Dilatation Catheter may be considered substantially equivalent to the predicate Cordis Jupiter™ and Cordis OPTA 5™ PTA Catheters.



DEC 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sudan Silavin, Ph.D.
Senior Regulatory Affairs Coordinator
Guidant Corporation
3200 Lakeside Drive
P.O. Box 58167
Santa Clara, CA 95054

Re: K983055
Trade Name: RX VIATRAC™ 14 Peripheral Dilatation Catheter
Regulatory Class: II
Product Code: LIT
Dated: November 20, 1998
Received: November 23, 1998

Dear Dr. Silavin:

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, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to

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

Indications for Use Statement

510(k) Number (if known): _____

Device Name: **RX VIATRAC™ 14 Peripheral Dilatation Catheter**

Indications for Use:

The RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated for dilatation of stenoses in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, the RX VIATRAC™ 14 Peripheral Dilatation Catheter is indicated for balloon dilatation of the PALMAZ™ P204 stent following implantation. It is not intended for use in the coronary vasculature.

Tara A. Rep

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K983055

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter _____

(Optional Format 1-1-96)