

JAN 27 2000

510(k) SUMMARY

K993639

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
Telephone: 408-235-3995
Fax: 408-235-3743
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: RX VIATRAC™ 14
Peripheral Dilatation Catheter (K983055)
Cordis OPTA 5™ PTA Catheter (K972825)

4. Device Description:

The RX VIATRAC™ 18 and the OTW VIATRAC™ 18 Peripheral Dilatation Catheters were developed in parallel as two platforms, a Rapid Exchange (RX) platform and an Over-the-Wire (OTW) platform. The distal 20 cm of both catheters are identical however, the proximal portions are modified to accommodate either the RX or OTW platform.

The RX catheter is a rapid exchange catheter with an integrated shaft system. The design is based upon the RX VIATRAC™ 14 Peripheral Dilatation Catheter, manufactured by Guidant (K983055, 12/30/98). The RX VIATRAC™ 18 Peripheral Dilatation Catheter has catheter lengths of 75 and 135 cm, with balloon diameters of 6.0, 7.0, 8.0, 9.0 and 10.0 mm.

The OTW platform is an over-the-wire, coaxial design catheter that is similar to that of the RX catheter. However, the OTW catheter has an inner member extending the entire length of the catheter, and therefore has no mid-catheter junction. The OTW VIATRAC™ 18 Peripheral Dilatation Catheter has catheter lengths of 75 and 135 cm, with balloon diameters of 6.0, 7.0, 8.0, 9.0 and 10.0 mm.

The XCELON™ balloon, which is identical on both RX and OTW VIATRAC™ 18 Peripheral Dilatation Catheters 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.

5. **Intended Use:**

The RX VIATRAC™ 18 Peripheral Dilatation Catheter is intended:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries)
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post deployment optimization of the 28 mm GUIDANT MEGALINK™ Biliary Stent (6.0 to 10.0 mm diameters).

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is intended:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries)
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post deployment optimization of the 28 mm GUIDANT MEGALINK™ Biliary Stent (6.0 to 10.0 mm diameters).

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 RX VIATRAC™ 14 Peripheral Dilatation Catheter and the OPTA 5™ PTA Catheter. 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 and OTW VIATRAC™ 18 Peripheral Dilatation Catheters met acceptance criteria and performed in a manner equivalent to the predicate RX VIATRAC™ 14 Peripheral Dilatation Catheter and the Cordis OPTA 5™ PTA Catheter. No new safety or effectiveness issues were raised during the testing program.

8. Conclusions:

Since the new RX and OTW VIATRAC™ 18 Peripheral Dilatation Catheters have 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™ 18 Peripheral Dilatation Catheter and the OTW VIATRAC™ 18 Peripheral Dilatation Catheter may be considered substantially equivalent to the predicate RX VIATRAC™ 14 Peripheral Dilatation Catheter and Cordis OPTA 5™ PTA Catheter.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2000

Susan Silavin, Ph.D.
Senior Regulatory Affairs Coordinator
Guidant Corporation
P.O. Box 58167
Santa Clara, CA 95052-8167

Re: K993639
Trade Name: RX and OTW VIATRAC 18 Peripheral Dilatation
Catheter
Regulatory Class: II
Product Code: LIT
Dated: October 27, 1999
Received: October 28, 1999

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 (Premarket 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.

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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) 594-4646. 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 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,



Celia M. Witten, Ph.D., M.D.
Acting 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): K993639

Device Name: RX VIATRAC™ 18 Peripheral Dilatation Catheter
OTW VIATRAC™ 18 Peripheral Dilatation Catheter

Indications for Use:

The RX VIATRAC™ 18 Peripheral Dilatation Catheter is intended:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries)
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post deployment optimization of the 28 mm GUIDANT MEGALINK™ Biliary Stent (6.0 to 10.0 mm diameters).

The OTW VIATRAC™ 18 Peripheral Dilatation Catheter is intended:

- To dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries)
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- For post deployment optimization of the 28 mm GUIDANT MEGALINK™ Biliary Stent (6.0 to 10.0 mm diameters).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-1-96)

Christopher Allen for Witten