

K9 70396

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510(k) SUMMARY

AUG 29 1997

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510(k) SUMMARY

AUG 29 1997

A. Introduction

This 510(k) is for the new Rotablator® System with the RotaLink™ Exchangeable Catheter (referred to as the A21 Rotablator system throughout this summary). The A21 Rotablator system is designed to allow for the exchange of the catheter by dividing the advancer into two components: an advancer with a short drive shaft and connector, and a catheter with a long drive shaft and connector. The indications for use of this device remain the same.

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Preparation Date: January 23, 1997

Device Common Name: Rotational Angioplasty System
Device Proprietary Name: Rotablator® Rotational Angioplasty System with the RotaLink™ Exchangeable Catheter
Classification Name: Catheter, Peripheral, Atherectomy (per 21 CFR 870.4875)
Classification Panel: Cardiovascular

Manufacturing Facilities: Boston Scientific Corporation Northwest Manufacturing Center, Inc.
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B. Device Description

The Rotablator® Rotational Angioplasty system uses a high speed, rotating, diamond-coated burr to ablate occlusive material and restore luminal patency. The burr spins at 140,000-190,000 RPM and ablates material into very fine particles that are carried distally and removed via the reticuloendothelial system. The A21 Rotablator system comprises four main components: advancer, catheter with diamond-coated burr, console and foot pedal, and guide wire.

The advancer houses the air turbine and functions as a guide for the sliding elements that control burr advancement. The turbine is designed with low torque so that it will stall if it

encounters resistance. This feature prevents inadvertent damage to the artery. The advancer has an air-actuated guide wire brake which is automatically actuated when the operator steps on the foot pedal to turn on the advancer. This feature prevents movement of the guide wire when the drive shaft is turning.

The catheter consists of the burr and drive shaft, the sheath, and the catheter body. The burr is attached to the end of the flexible drive shaft which is connected to an air turbine and powered by compressed air or nitrogen. The drive shaft, which has a central lumen for a guide wire to pass through, is flexible. This feature facilitates passage through tortuous arteries and around multiple sharp bends, and permits the burr to reach lesions in small distal arteries. The catheter is covered by a Teflon™ sheath which protects arterial tissue from the spinning drive shaft and permits the passage of saline to lubricate and cool the drive shaft. A contrast agent can be delivered to the lesion site by flowing between the sheath and the guide catheter. The A21 peripheral catheter will be available in burr sizes ranging from 1.5 mm to 4.0 mm. The various sizes allow for maximum debulking when treating lesions in small or distal vessels as well as those in larger arteries.

The Rotablator catheter tracks over a guide wire which is passed through the lesion to be treated. The guide wire directs the catheter to the lesion and keeps it aligned within the artery. This allows the catheter tip to be redirected as it progresses around bend points, thus decreasing the possibility of the tip contacting the outer wall and potentially causing tissue damage. The guide wire has a radiopaque spring tip which facilitates its passage through the vasculature, minimizes trauma to the vessel, and makes progress visible on fluoroscopy.

The console monitors and controls the rotational speed of the burr and continuously provides the operator with performance information during the procedure. The console has two modes of operation: a high speed for ablation and a lower speed for catheter exchange (i.e., Dynaglide™ mode). In the Dynaglide mode, the drive shaft rotates at a reduced speed of 50,000-90,000 RPM, thus allowing the physician to defeat the guide wire brake and allow the guide wire to remain in place while the catheter is withdrawn. This feature facilitates removal of the catheter from the coronary arteries. The Rotablator console is powered by house current, however, no electricity is transmitted to the advancer or to the patient.

The foot pedal is the on/off control for the advancer air turbine and is mounted in a protective shroud to inhibit accidental actuation. The pedal is fitted with a valve that vents any compressed gas left in the foot pedal hose when the pedal is released, permitting the burr to stop rapidly. The foot pedal also has a toggle switch for activating and deactivating the lower speed used during catheter exchange.

The compressed gas system consists of a regulator mounted on a compressed gas cylinder and a supply hose leading to the control console inlet.

C. Intended Use

The Rotablator system is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for bypass graft surgery or percutaneous transluminal angioplasty.

D. Comparison to Predicate Device

The A21 Rotablator system is substantially equivalent to the currently marketed Rotablator system (referred to as A19 throughout this summary). The difference between the two devices is two functional changes and several minor modifications in material and design of the A21, none of which affects function. In addition, the largest burr used in the A19 system, 4.5 mm, will not be manufactured for the A21 system.

The following table summarizes the functional and non-functional changes.

	A19	A21
Functional	Advancer and catheter one unit. No docking port.	Advancer and catheter two separate units. Docking port to hold wireClip.
Design and Material Changes (no functional impact): Drive Mechanism	Adhesive bonds between bearings, turbine shaft, and bearing housing. Retro-reflector press fit onto turbine shaft. Cyanoacrylate adhesive bond between turbine shaft and pump shaft. Epoxy bond between pump shaft and drive coil.	Press fit of turbine components into turbine housing. Retro-reflector slip fit onto turbine shaft. Ultraviolet cure adhesive bond between turbine shaft and pump shaft. Laser weld between drive coil and pump shaft and connectors.
Design and Material Changes (no functional impact): Fluid Path	Stainless steel pump rotor. Polyetherimide front plug. FEP small hypo tube liner. Cyanoacrylate adhesive bond between pump rotor and pump shaft. NA Diamond grit size: .002-.0031"	Polysulfone pump rotor. Polysulfone front plug. PTFE small hypo tube liner (same material as large hypo tube liner). Pump rotor press fit onto pump shaft or pump rotor insert molded to pump shaft. Catheter connection made of ABS; new material to fluid path. Diamond grit size: .0008-.0012"

1. Functional Changes

a. Catheter and Drive Shaft Connections

In the A21, the drive shaft is made up of two components: the short drive shaft, which is part of the advancer, and the long drive shaft, which is part of the catheter. In the A19, the drive shaft is a single component, and the catheter and advancer are a single unit. By allowing for the separation of the catheter from the advancer, several catheters with various burr sizes can be attached to a single advancer during a procedure. This change is incorporated to facilitate the multiple-burr treatment regime used by many physicians. The connection of the catheter to the advancer involves two systems: drive shaft connection plus slide tube, and the catheter connection. Once the drive shaft and catheter are connected to the advancer, the A21 advancer/catheter is functionally equivalent to the A19 advancer/catheter.

b. Docking Port

The A21 has a new feature, the docking port. The docking port facilitates conducting the clinical procedure in several ways. First, the wireClip® torquer can be inserted into the docking port, where it is held during the procedure. Second, during an exchange procedure, when the brake defeat button has been depressed, the torquer can be inserted further into the docking port to serve two functions: the docking port holds the torquer in place which prevents spinning of the guide wire, and the torquer prevents the brake from engaging, even when the brake defeat button is not being depressed. This configuration enhances safety and efficiency because neither the operator nor additional personnel are required to hold the torquer.

2. Design and Material Modifications to Functional Components

The advancer body has been changed from a solid machined plastic tube to a two-piece snap together shell, i.e., a top and a bottom. The catheter body also is a two piece snap together assembly.

3. Performance

All performance specifications for the A21 Rotablator system such as speed, infusate flow, torque, etc., are identical or more stringent than those for the A19 Rotablator system, therefore, the A21 is equivalent in performance to the A19 Rotablator system.

E. *In Vitro* Tests

Bench testing was done to show that the performance of the peripheral A21 system conforms to product specifications and that it is as safe and effective as the current peripheral A19 system. Testing was conducted on performance characteristics that are influenced by the catheter's configuration and are clinically relevant.

Using statistically valid sample sizes, the testing showed with 95% confidence that there is a 99% probability that the following performance specifications will be met: dynamic stall torque, steady state stall torque, and distal flow rate.

The test also indicated the following:

- ◆ With 95% confidence, there is a 99% probability that the functional life of the catheter will be 20 minutes.
- ◆ The difference in lesion crossing time between the A19 and the A21 were not statistically significant.

Additional testing was done for further comparison of clinically relevant performance characteristics: speed versus console pressure, and stall torque versus console pressure. Five A19 1.5 mm burrs and five A19 3.0 mm burrs were tested - the two burr sizes allow for testing the two types of turbine nozzles in the A19. For the A21 system, one advancer and five catheters were tested. Only one burr size was used for the A21 since they are used with the same type of turbine nozzle.

The results of the speed versus pressure test indicate that the A21 runs slower than the A19 at a given console pressure. The results of the stall torque versus pressure test indicate that at any given console pressure lower than 50 PSI, the A21 delivers less torque than does the A19. However, at console pressures of 50 PSI or greater, this difference decreases. These performance differences between the A19 and the A21 are not significant from the user's point of view and does not affect the A21's effectiveness because the maximum suggested operational speed of 180 KRPM can still be attained. Also, the higher operational pressures

required to attain a given speed for the A21 will serve to offset the lower torques of the A21 since torque increases with pressure.

F. Biocompatibility

A biological evaluation was performed on the A21 Rotablator system to give a high degree of assurance that the final product will be safe for human use. These tests included material characterization, cytotoxicity, pyrogenicity and hemocompatibility assays conducted under Good Laboratory Practices (GLP). The infusion pathway portion of the device was evaluated as a whole composite following two EtO sterilization cycles. The A21 Rotablator system was found to be compatible with biological systems.

G. Sterilization

Following final packaging and labeling, finished devices are 100% ethylene oxide (EtO) sterilized to achieve a sterility assurance level (SAL) of 10^{-6} , or one nonsterile unit out of one million. The Rotablator device is nonpyrogenic based on the Limulus Amebocyte Lysate (LAL) assay.

H. Clinical Tests

Clinical studies were not conducted on the A21 design. As part of the design criteria for the A21 Rotablator system, it was specified that the therapeutic benefit of the current A19 Rotablator system not be changed. All parts that come in contact with the patient are, therefore, the same as the corresponding parts in the current system, specifically the burr, the drive shaft, and the sheath material. Any changes made to the system to facilitate the separable catheter design, improve manufacturability and reliability, and reduce the unit cost of the device, have no significant impact on the therapeutic benefit of the device, therefore, no clinical study was required.

The aspects of the device that relate to patient safety are 1) biocompatibility of the materials in the fluid contact path, 2) device sterility, 3) interaction between the burr and the vessel wall, 4) infusion of saline at the treatment site, and 5) functionality of the brake system. All of these aspects of the A21 have been tested and show the device to be safe and the clinically relevant parameters unchanged from those of the A19.



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AUG 29 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Re: K970296
Peripheral Rotablator® Rotational Angioplasty System with the
RotaLink™ Exchangeable Catheter
Regulatory Class: II (Two)
Product Code: MCW
Dated: May 29, 1997
Received: June 2, 1997

Dear Ms. Johnson:

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 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 pre-market 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.

Page 2 - Ms. Diane Johnson

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) 594-4648. 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" (21 CFR 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/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

SECTION III

INDICATIONS FOR USE

Device: Rotablator® Rotational Angioplasty System with RotaLink™ Exchangeable Catheter

The Rotablator system is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for bypass graft surgery or percutaneous transluminal angioplasty.

Quane Johnson

For Boston Scientific Corporation Northwest Technology Center

January 23, 1997
Date

Q. Danubon for T. Ryan 8/29/97
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K970296