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TABLE OF CONTENTS

510(k) SUMMARY

A. Introduction 2

B. Device Description 2

C. Intended Use 3

D. Comparison to Predicate Device 4

E. In Vitro Tests 5

510(k) SUMMARY

A. Introduction

This 510(k) is for two new guide wires that are designed for use with the Rotablator® Rotational Angioplasty System.

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Device Common Name:	Rotational Angioplasty System Guide Wires
Device Proprietary Name:	Rotablator® System's Guide Wire Line: Support RotaWire™; Rail RotaWire™
Classification Name:	Catheter, Peripheral, Atherectomy (per 21 CFR 870.4875) Guide Wire, Angiographic, Accessory
Classification Panel:	Cardiovascular
Manufacturing Facility:	Heart Technology Manufacturing, Inc. 17425 N.E. Union Hill Road Redmond, WA 98052

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 burr is driven by a flexible helical drive which has a central lumen through which a guide wire passes. The drive shaft is connected to an air turbine which is powered by compressed air or nitrogen.

The guide wire that is used with this system can be separately advanced and steered past an occlusive lesion. The guide wire has a radiopaque spring tip that facilitates its passage through the vasculature, minimizes trauma to the vessel, and makes its progress visible.

The sheath covering the drive shaft protects arterial tissue from the spinning drive shaft and permits the passage of saline to lubricate and cool the spinning drive.

The advancer functions as a housing for the air turbine and as a guide for the sliding elements that control burr extension.

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.

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 rapid stopping of the burr. The foot pedal also has a toggle switch for activating and deactivating the lower speed 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 Rotablator system's new RotaWire guide wires are substantially equivalent to the currently marketed Type C guide wire. The differences in the RotaWire wires compared to the Type C are summarized in Table 1. The indications for use remain the same. No change to the Rotablator advancer/catheter or the console is being proposed.

Feature	Type C	RotaWire
Wire Profile	Linear taper in the distal 1.60"	Support - Compound tapered profile in the distal 18.0" Rail - Taper in the distal 3.1"
Wire Material	304 Stainless Steel	304 Stainless Steel
Spring Tip Material	Pt-8%W alloy	Pt-8%W alloy or Pt-10%Ni alloy
Spring Tip Length	1.40"	1.10"
Spring Tip Inner Diameter	.0090"	.0055 to .0060"
Spring Tip Outer Diameter	0.017"	0.014"

Table 1. Design Comparison of Type C and RotaWire Guide Wires

E. In Vitro Tests

A series of bench tests were done to characterize the performance of the RotaWire guide wires in a clinical setting. The results of these tests demonstrate that the design of the RotaWire guide wires is robust, and that these guide wires are capable of performing satisfactorily with the Rotablator system in the treatment of lesions as an alternative to the Type A and Type C guide wires that are currently used. Test results are summarized in Table 2.

In addition to the tests summarized in Table 2, toxicity tests were completed on a Pt-10%Ni alloy because this material was chosen as an alternative to the Pt-8%W alloy currently used for the spring tips in HTI's guide wires.

	Support RotaWire	Rail RotaWire	Type C
Tensile strength (grams) a) weld joint b) solder joint	a) minimum 472 nominal 685 maximum 808	No Test[1]	No Test
	b) minimum 2337 nominal 2390 maximum 2276	No Test[1]	No Test
Torque Strength (oz.- in.)	minimum .076 nominal .105 maximum .143	minimum .077 nominal .107 maximum .153	.185
Torqueability[2] (proximal to distal turns)	minimum 1.75 to 1 nominal 1.75 to 1 maximum 2.25 to 1	minimum 2.75 to 1 nominal 2.75 to 1 maximum 3 to 1	3.25 to 1
Tip Flexibility (in.) a) cantilevered 1.5"; force =0.20 gm b) cantilevered 3.1"; force =0.20 gm c) cantilevered 6.1"; force =0.20 gm	a) .79	.79	.71
	b) 1.49	1.29	1.00
	c) 3.95	3.27	3.27

Table 2. Engineering Test Comparison of Type C and RotaWire Guide Wires

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[1] Weld and solder joints for the Support and Rail RotaWires are dimensionally identical, therefore, only the Support RotaWire was tested.

[2] A one-to-one torque response is desirable, that is, for one revolution of the proximal end (outside the body), the distal spring tip in the vessel should also rotate once.