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510(k) SUMMARY

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A. Introduction

This 510(k) is for a new line of guide wires which 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® Rotational Angioplasty System Rotablator® System's Guide Wire Line: HTI Floppy; HTI Floppy II; HTI Standard

Classification Name: Catheter, Peripheral, Atherectomy (per 21 CFR 870.4875) Guide Wire, Angiographic, Accessory

Classification Panel: Cardiovascular

Manufacturing Facilities: Heart Technology Manufacturing, Inc.
2515 140th Avenue NE.
Bellevue, WA 98005
and
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 HTI guide wires are substantially equivalent to the currently marketed Type A and Type C guide wires. The differences in the HTI wires compared to the currently marketed Types A and 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	Types A and C	HTI
Wire Profile	Linear taper in the distal 1.60"	Compound tapered profile in the distal 18.0"
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	Type A 1.05" Type C 1.40"	Floppy .85" Floppy II 1.10" Standard .85"
Spring Tip Inner Diameter	.0090"	.0055 to .0060"
Spring Tip Outer Diameter	0.017"	0.014"

Table 1. Design Comparison of Types A and C, and HTI Guide Wires

E. In Vitro Tests

A series of bench tests were done that characterize the performance of the HTI guide wires in a clinical setting. The results of these tests indicate that the HTI guide wires are safe and reliable. 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.

		Floppy	Floppy II	Standard	Type A	Type C
Tensile Force (grams) a) weld joint b) solder joint	a)	315	364	603	182	No Test
	b)	1132	1373	1837	2384	No Test
Torque Strength (turns to failure)		11.6	9.7	15	No Test	18.8
Torqueability[1] (proximal to distal turns)		1.75 to 1	No Test	2 to 1	3.25 to 1	No Test
Tip Flexibility (mm) a) cantilevered 1.5"; force =.18 gm b) cantilevered 3.1"; force =.18 gm c) cantilevered 6.1"; force =.16 gm	a)	15.7	20.7	14	6.0	19.0
	b)	44.0	47.5	No Test	25.1	20.0
	c)	97.8	102.9	No Test	76.2	71.1
Wear Test	All wire configurations passed wear test. Success criteria: (1) guide wire does not fail catastrophically, and (2) at end of two minute test, advancer speed ≥ 150,000 RPM.					
Heart Model	In this qualitative assessment of pushability and steerability the Floppy and Floppy II were compared to Type C, and the Standard was compared to Type A. All A Plus wires were found more maneuverable than the Types A and C.					

Table 2. Engineering Test Comparison of Types A and C, and HTI Guide Wires

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[1] 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.

F. Clinical Tests

The clinical investigation included 147 sequentially enrolled patients with coronary artery disease between July 1994 and December 1994. The inclusion and exclusion criteria are consistent with the Investigational Plan previously submitted in G940032. The contraindications and precautions are consistent with the approved *Instructions for Use for the Rotablator System.* The patients' demographic characteristics are similar to those in the study involving the originally approved guide wires, although the current population includes patients with more pronounced risk factors.

Descriptive statistical analysis showed that the complication rates associated with the use of the HTI guide wires and the Types A and C guide wires are not significantly different with the exception of spasm, abrupt closure post catheterization lab, and access site bleeding of significance. These complications are not considered to be related to the guide wire. It may be hypothesized that the increase in these complications can be attributed to the patient population characteristics. In general, the Rotablator system is currently utilized more often to treat complex lesions (as compared to the original PMA population). It has been shown that both procedural success and complications are a function of lesion classification.[2] Because lesions were characterized differently in the two studies, it is not possible to directly compare lesion classification between the current study and the previous study. However, the lesion characteristics indicate that the current lesions would fall into a higher lesion classification than those in the original PMA population.

No patients were discontinued from the study. There was one guide wire fracture during the investigation. Although these clinical data are from coronary use of the

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[2] Ellis, et al, Circulation, Vol 89, No 2, Feb 1994. Relation of Clinical Presentation, Stenosis, Morphology, and Operator Technique to the Procedural Results of Rotational Atherectomy Facilitated Angioplasty.

Rotablator system, the conclusions of safety and efficacy also apply to the peripheral Rotablator system since the coronary procedure represents a worst case situation.

The preceding summaries demonstrate that the design of the HTI guide wires is robust, and that they 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.