SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Coronary Stent System

Device Trade Name: Driver™ Over-The-Wire, Rapid Exchange and Multi-Exchange Coronary Stent System

Applicant's Name and Address: Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403
USA

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P030009

Date of Notice of Approval to Applicant: October 1, 2003

II. INDICATIONS FOR USE

The Medtronic Driver™ Over-The-Wire, Rapid Exchange, and Multi-Exchange Coronary Stent Systems (hereinafter called the Driver™ Coronary Stent System) are indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic lesions with reference vessel diameters of 3.0 – 4.0 mm and ≤ 30 mm in length using direct stenting or pre-dilatation. Outcome beyond 270 days for this permanent implant is unknown at present.

III. DEVICE DESCRIPTION

The Medtronic Driver™ Coronary Stent System is comprised of two components: the Stent and the Delivery System. The Driver™ stent is identical despite which delivery system it is mounted on.

The Driver™ stent consists of a series of 1.0 mm segments that are constructed from a continuous toroid ring manufactured from a Co-Ni-Cr-Mo alloy conforming to ASTM F 562-00. The ring is formed into alternating upper and lower crowns with 10 radiused crowns per end connected by axial struts for a total of 20 crowns and 20 axial struts in a zigzag pattern.

The use of a new alloy facilitates the implementation of thinner struts without affecting the radial strength or radiopacity of the stent. Unlike 316L stainless steel, the new alloy does not contain significant levels of iron (1.0 percent by weight maximum), thereby enhancing MRI compatibility. In addition, the radiopacity of the Co-Ni-Cr-Mo alloy is greater than that of 316L stainless steel, due primarily to increased levels of molybdenum. As such, the radiopacity of 316L stainless steel stents is maintained with the Co-Ni-Cr-Mo alloy stents even with thinner stent struts

The stent is mounted on one of three delivery systems. Each delivery system provides a means for delivering the stent through the coronary vasculature and, once in the desired location, expands the stent through balloon inflation. The three delivery systems available with the Driver™ stent are the Over-The-Wire (OTW), Rapid Exchange (RX) and Multi Exchange (MX) Delivery System.

All delivery systems have a minimal amount of working length extending beyond the stent on each side. The inner lumen of the catheter is designed to accommodate a maximum guidewire diameter of 0.014 inches.

Table 1 provides the product labeling specifications for the Medtronic Driver™ Coronary Stent and the three Delivery Systems

Table 1: Product Labeling Specifications for the Medtronic Driver™ Coronary Stent Systems

Product	Delivery System Type	Stent Diameter (mm)	Stent Length (mm)	Minimum Guiding Catheter Inner Diameter (inches)	Nominal Pressure (atm)	Rated Burst Pressure (atm)
Medtronic Driver™ Over-the-Wire Coronary Stent System	Over-the-Wire	3.0 3.5 4.0	9 12 15 18 24 30	.056	9	16
Medtronic Driver™ Rapid Exchange Coronary Stent System	Rapid Exchange	3.0 3.5 4.0	9 12 15 18 24 30	.056	9	16
Medtronic Driver™ Multi-Exchange MX Coronary Stent System	Multi-Exchange	3.0 3.5 4.0	9 12 15 18 24 30	.064	9	16

IV. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications

The Driver Coronary Stent System is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

Warnings and Precautions

A list of warnings and precautions can be found in the device labeling.

V. ALTERNATIVE PRACTICES AND PROCEDURES

Patients with early coronary artery disease receive exercise, diet, and drug therapy as appropriate. If the disease progresses, alternative practices specific to the treatment of coronary artery disease include: percutaneous transluminal coronary angioplasty (PTCA), drug therapy (e.g., thrombolytic agents, antiplatelet agents, and anticoagulant agents), Coronary Artery Bypass Graft Surgery (CABG), and stenting with other commercially available stents.

VI. MARKETING HISTORY

The Driver Coronary Stent System has been approved for commercial distribution in the European Union, Canada, China, Australia and Singapore. The Driver Coronary Stent System has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VII. SUMMARY OF PRECLINICAL STUDIES

Biocompatibility

All biocompatibility testing was performed in accordance with;

- Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices; published by the Interventional Cardiology Devices Branch, Division of Cardiovascular, Respiratory and Neurology Devices, Office of Device Evaluation in May 1995.
- ISO 10993, Biological Evaluation of Medical Devices

The following biocompatibility tests were conducted and passed on the Driver™ Coronary Stent System:

Biocompatibility Testing on Co-Ni-Cr-Mo alloy (Driver™ Stent)

Component	Biological Effect	Test	Criterion	Results
Stent Raw Material	Cytotoxicity	L929 MEM Elution Test-ISO	01-2293-G1 Results must indicate a grade of 2 or lower.	Pass
	Sensitization	Skin Sensitization Kligman Maximization test-ISO	01-2293-G11 No dermal inflammatory response greater than the control.	Pass
	Irritation	Intracutaneous Injection Test-ISO	01-2293-G8 No greater adverse reactions or responses when compared to the controls.	Pass
	Systemic Toxicity	System Injection test-ISO	01-2293-G9 No greater adverse reactions or responses when compared to the controls.	Pass
	Mutagenicity / Genotoxicity	Rodent Bone Marrow Micronucleus Assay-ISO	01-2293-G7 The test article must not induce a significant increase in the number of micronucleated cells when compared to controls.	Pass
		Chromosomal Aberration Assay-ISO	01-2293-G6 The test article must not induce a significant increase in reversion in the genomes of the organisms tested, when compared to controls.	Pass
		S. typhimurium/ E.coli Reverse Mutation Assay-ISO	01-2293-G5 Test article extracts must not be considered mutagenic when compared to controls.	Pass
	Implantation / Subchronic toxicity	Biocompatibility Implant Study	0052D640 P1056 No capsule formation or other adverse reaction to the implanted test article.	Pass
	Hemocompatibility	C3a Complement Activation Assay	01-2293-G3 The test article must not induce complement activation when compared to controls.	Pass

		Unactivated Partial Thromboplastin Time Assay-ISO	01-2293-G4 The test article must not significantly effect the clotting time of human plasma when compared to controls.	Pass
		In Vitro Hemocompatibility Assay-ISO	01-2293-G2 The test article must not adversely effect selected hematological parameters of human blood when compared to controls.	Pass
	Pyrogenicity	Rabbit Pyrogen Test (Material Mediated)-ISO	01-2293-G10 No single animal must exhibit an increase of 0.5°C or more above its baseline temperature.	Pass
	Hemocompatibility	C3a Complement Activation Assay	01T 10878 01 The test article must not induce complement activation when compared to controls.	Pass
	Implantation / Subchronic toxicity	ISO Muscle Implantation, in 3 Rabbits (6 weeks), w/histopathology	01C 12404 00 No capsule formation or other adverse reaction to the implanted test article.	Pass

Biocompatibility Testing on Stent and Rapid Exchange Delivery System

Component	Type	Test	Criterion	Results
Stent and Delivery System	Cytotoxicity	L929 MEM Elution Test-ISO	01C 11441 00 Results must indicate a grade of 2 or lower.	Pass
	Sensitization	ISO Sensitization Study in the Guinea Pig	01C 11441 00 No dermal inflammatory response at the test sites greater than that seen in the control.	Pass
	Irritation	ISO Acute Intracutaneous Reactivity Study in the Rabbit	01C 11441 00 No adverse reactions or responses when compared to the controls.	Pass
	Systemic Toxicity	ISO Acute Systemic Toxicity in the Mouse	01C 11441 00 No greater adverse reactions or responses when compared to the controls.	Pass

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.