AUG 3 1 1999

K992569
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510(k) Summary for the Medtronic AVE Stent Delivery System

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of AMDA 1990 and 21 CFR 807.92.

Identification

The assigned 510(k) number is _____ .

Applicant:

Medtronic AVE, Inc.
Peripheral Technologies
2330 Circadian Way
Santa Rosa, California 95407
Contact: Susan L. Walton

Phone: (707) 591-7315 FAX: (707) 591-7406
e-mail: susan.walton@medtronic.com
Date submitted: July 30, 1999

Tradename:

Device Name: Medtronic AVE Bridge™ Stent
Model Numbers: B6028, B6028L, B7028, B7028L, B8028, B8028L, B9028, B9028L, B10028, B10028L
Classification Name: Catheter, Biliary and accessories

Section 513 Device Classification

Classification: Class II
Classification Panel: 78FGE

Equivalence

Medtronic AVE claims substantial equivalence to the Peripheral AVE Stent Delivery System - For Use In Biliary Indication.

Intended Use

The Medtronic AVE Bridge™ Stent is intended to maintain patency of a bile duct which is occluded by a malignant tumor.

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510(k) Summary for the Medtronic AVE Stent Delivery System, Continued

Description of Device

The Bridge™ Stent consists of a balloon expandable intralumenal stent premounted onto the balloon of an over-the-wire delivery catheter. The device has two radiopaque platinum markers imbedded on the inner shaft (at each end of the stent) to aid in the placement of the stent during fluoroscopy. The delivery system is compatible with 0.035" guidewires and has a useable length of 75cm to 120cm. The device is provided in a sterile package.

Size range:	Diameters:	6.0 to 10.0 mm
	Lengths	28 mm

Comparison Table

This device is intended to maintain patency of a bile duct which is occluded by a malignant tumor.

Characteristic	Subject Device	Predicate Device
Intended Use	This device is intended to maintain patency of a bile duct which is occluded by tumor.	This device is intended to maintain patency of a biliary duct which is occluded by tumor.
Physical Characteristics (stent)	316L stainless steel balloon expandable premounted stent • Diameters 6 - 10mm • Length 28mm	316L stainless steel balloon expandable premounted stent • Diameters 5 - 10mm • Lengths 17 to 60mm
Physical Characteristics (delivery system)	Balloon delivery system • PTA catheter (PET) • 5.3 to 5.8 F shafts • 75 to 120cm lengths • 0.035" guidewire Ø	Balloon delivery system • PTA catheter (PET) • 5.3 to 5.8 F shafts • 75 to 90cm lengths • 0.035" guidewire Ø
Anatomical site	Bile duct	Biliary duct
Target population	Patients with bile duct obstruction caused by malignant tumor.	Patients with biliary duct obstruction caused by malignant tumor.

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510(k) Summary for the Medtronic AVE Stent Delivery System, Continued

Performance Testing

The subject device for this 510(k) is identical to the predicate device with the exception of an alternate stent segment (component) and a new stent length. The flexible Medtronic AVE Stent was found to be substantially equivalent in K983008 approved November 25, 1998. Performance testing was conducted on the subject device for the purpose of direct comparison to the predicate device. The testing was chosen to highlight any differences between the subject device and the predicate device. The balloon materials have not been changed. The useable catheter length may be either 75 cm (cleared in K983008) or a new length, 120 cm. The manufacturing process is not changed.

Test	Purpose
• Balloon Burst • Balloon Deflation Time • Crossing Profile	To compare the stent/delivery system of the subject device and the predicate device. The data will support a premarket notification for the Medtronic AVE Stent Delivery System - For Use In Biliary Indication.
• Diameter versus Inflation Pressure	To create and compare the compliance curves for the subject device and the predicate device. The data will support a premarket notification for the Medtronic AVE Stent Delivery System - For Use In Biliary Indication.
• Stent Free Area • Stent Length • Stent Recoil	To compare the stent dimensional data for the subject device and the predicate device. The data will support a premarket notification for the Medtronic AVE Stent Delivery System - For Use In Biliary Indication.

Conclusions

The performance testing and comparison of the Peripheral AVE Stent Delivery System and the Medtronic AVE Bridge™ Stent prove the two devices are substantially equivalent.

Additional Information

The summary includes any other information reasonably deemed necessary by FDA.

Biocompatibility

The materials used in the Medtronic AVE Bridge™ Stent passed all biocompatibility tests.

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510(k) Summary for the Medtronic AVE Stent Delivery System, Continued

Sterilization

The Medtronic AVE Bridge™ Stent is provided sterile.

The Medtronic AVE Bridge™ Stent is not intended for sterilization or reuse/resterilization by the user.

Medtronic AVE validates the sterilization method for its stent delivery systems according to the ANSI/AAMI/ISO 11137 - 1994, Method I: Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization. The Sterility Assurance Level (SAL) is 10^{-6}.

The Medtronic AVE Bridge™ Stent is labeled pyrogen free. LAL testing is performed daily in compliance with FDA guidance on Validation of Limulus Amebocyte Lysate Test as an End Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices - Section V - 2 Inhibition and Enhancement Testing as part of Medtronic AVE's product release criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1999

Ms. Susan L. Walton
Regulatory Coordinator
Medtronic AVE, Peripheral Technologies
2330A Circadian Way
Santa Rosa, CA 95407

Re: K992569
Medtronic AVE Bridge™ Stent System (Hi-Flex) – Biliary Indication
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: July 30, 1999
Received: August 2, 1999

Dear Ms. Walton:

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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/dsma/dsmamain.html".

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992569

Device Name: Medtronic AVE Bridge™ Stent System (Hi-Flex) – Biliary Indication

FDA's Statement of the Indications For Use for device:

The Medtronic AVE Bridge™ Stent System (Hi-Flex) – Biliary Indication is intended to maintain patency of a bile duct which is occluded by a malignant tumor.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992569

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)