Summary of Safety and Effectiveness

K994141

Trade Name:

Medtronic AVE Solstice ™ Temporary Occlusion Balloon System.

Manufacturer:

Medtronic AVE, Inc.
3576 Unocal Street
Santa Rosa, California, 95403

Contact: Sonny Yamasaki

Establishment Registration Number: 2953200

Classification Name:

Catheter, Intravascular Occluding, Temporary (21 CFR 870.4450)
Wire, Guide, Catheter (21 CRF 870.1330)

Device Classification:

Solstice: Class II (21 CFR 870.4450) Panel: Interventional Cardiovascular DCRND
QS 10: Class II (21 CFR 870.1330) Panel: Interventional Cardiovascular DCRND

Intended Use and Product Description:

The Medtronic AVE Solstice Temporary Occlusion Balloon Catheter and QS 10 Guidewire System (here after referred to as Solstice and/or QS 10) is designed for use in blood vessels where temporary occlusion is desired. Solstice and QS 10 are intended to be used together for temporary vascular occlusion in selectively stopping or controlling blood flow in the peripheral, cerebral, and visceral vasculature.

The Solstice is a single lumen balloon catheter that uses the QS 10 guidewire to occlude the central lumen and allow inflation of the balloon. This is accomplished by advancing any part of the QS 10 through the catheter. The single lumen then becomes occluded allowing fluid to fill the balloon.

Sterilization, Packaging, and Pyrogenicity:

The Solstice Temporary Occlusion Balloon System is packaged in individual dispensing hoops which are sealed inside their own labeled Tyvek bags. The Solstice System is created by placing a Solstice sterile pouch, a QS 10 Guidewire sterilized pouch and the IFUs (one for Solstice and one for QS 10) in a carton with a Solstice System Label. QS 10 Guidewire packaging has also been validated for being sold individually.

Solstice Catheter is sterilized using EtO and the QS 10 is e-beam irradiation sterilized.

Substantial Equivalence:

The Medtronic AVE Solstice Temporary Occlusion Balloon System is substantially equivalent to the MTI, Equinox™ Occlusion Balloon System (K990487) which includes a 0.10" guide wire (SilverSpeed: K982543)

Establishment of equivalence is based on similarities of intended use, design, and physical characteristics as evaluated by physical bench testing, biocompatibility, and animal studies.

Summary of Safety and Effectiveness:

Safety and effectiveness were evaluated through biocompatibility testing, reliability testing, mechanical testing, and animal studies. Testing was conducted on final, sterilized Solstice Catheters and QS 10 Guidewires with guidance in part from "PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents," May 1995. The tests were used to assess the mechanical properties of the Solstice Catheter and QS 10 Guidewire. Based on in-vitro and in vivo testing results, Medtronic AVE believes the Solstice and QS 10 are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2000

Sonny Yamasaki, Ph.D.
Medtronic AVE, Inc.
3576 Unocal Street
Santa Rosa, CA 95403

Re: K994141
Medtronic AVE Solstice™ Temporary Occlusion Balloon System
Regulatory Class: II (two)
Product Code: 74 MJN
Dated: April 28, 2000
Received: May 1, 2000

Dear Dr. Yamasaki:

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. 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 (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.

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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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

Company Name:	Medtronic AVE
Device Name:	Solstice™ Balloon Temporary Occlusion Catheter Balloon System
Indication for Use:	The Medtronic AVE Solstice™ Solstice Balloon Temporary Occlusion System is intended to be used for temporary vascular occlusion in selectively stopping or controlling blood flow in the peripheral, cerebral, and visceral vasculature.

Brian E. Ajamian

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