PeripheralAVE

Peripheral AVE Biliary Stent System

510(k) Summary of Safety and Effectiveness

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

The assigned 510(k) number is: K983008

GENERAL INFORMATION

Applicant:

Date:	27 August, 1998
Name:	Peripheral AVE
Address:	2330A Circadian Way Santa Rosa, CA 95407
Contact:	Paul A. Meyer, P.E., RAC
Phone Number:	(707) 541-3254
FAX Number:	(707) 543-5454

Trade Name:

Device Name:	Peripheral AVE Biliary Stent System
Model Numbers:	TBD
Classification Name:	Catheter, Biliary and accessories

Section 513 Device Classification:

Classification	Class II
Classification Panel:	78FGE

EQUIVALENCE

Peripheral AVE claims substantial equivalence to the Johnson & Johnson Interventional Systems' PALMAZ™ Balloon-Expandable Stent.

INTENDED USE

The Peripheral AVE Biliary Stent System is intended for use in patients who are eligible for percutaneous transluminal angioplasty (PTA) to maintain patency of a biliary duct which is occluded by tumor.

The Peripheral AVE Bilairy Stent System is indicated for palliative treatment of biliary duct strictures caused by malignant tumors.

DEVICE DESCRIPTION

The Peripheral AVE Bilairy Stent System consists of a balloon-expandable intraluminal stent premounted onto the balloon of an over-the-wire delivery catheter. The Peripheral AVE Bilairy Stent System has two radiopaque platinum markers imbedded in 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 75 cm to 90 cm. The Peripheral AVE Bilairy Stent System is provided enclosed in a sterile package.

Size Range:

Diameters – 6.0 mm to 10.0 mm
Lengths – 17 mm to 60 mm

Comparison to Predicate Device:

Per 807.92(a)(6), the 510(k) summary contains a summary of the technological characteristics of your device compared to the predicate device.

Characteristic Compared	AVE Bridge™ Stent System	PALMAZ™ Balloon-Expandable Stent
Intended Use:	The Peripheral AVE Biliary Stent System is intended for use in patients to maintain patency of a biliary duct which is occluded by tumor. The Peripheral AVE Biliary Stent System is indicated for palliative treatment of biliary duct strictures caused by malignant tumors.	The device is a permanent implant intended to maintain patency of a bile duct which is obstructed by scar tissue or tumor.
Physical Characteristics (Stent):	316L stainless steel balloon expandable stent - premounted • Diameters - 6 mm to 10 mm • Lengths - 16 mm to 60 mm	316L stainless steel balloon expandable stent - premounted or unmounted • Diameters - 4 mm to 12 mm • Lengths - 9 mm to 40 mm
Physical Characteristics (Delivery catheter):	balloon delivery system - PTA catheter • 5.3-5.8 F shaft size • 75 cm to 90 cm length • 0.035 in. Guidewire diameter	balloon delivery system - PTA catheter • 5 F to 7 F shaft size • 75 cm length • 0.035 in. Guidewire diameter for unmounted stents - Medi-tech PE-MT™ PTA balloon catheters • 5 F to 9 F shaft size • 60 cm to 120 cm length • 0.035 in. Guidewire diameter
Anatomical Sites:	Biliary Ducts	Biliary Ducts
Target Population:	Patients with biliary duct obstruction caused by malignant tumor	Patients with biliary duct obstruction caused by tumor or scar tissue

Performance Testing:

Per 807.92(b)(1) If the determination of substantial equivalence is also based on an assessment of performance data, the summary includes a brief discussion of the non clinical tests and how their results support a determination of substantial equivalence

1. **Peripheral AVE Biliary Stent System vs JJIS Palmaz™ Balloon-Expandable Stent – Balloon Performance Study**

   Purpose:
   To compare the minimum burst pressure and deflation times of the Peripheral AVE Biliary Stent System balloons to the PALMAZ™ Balloon-Expandable Stent balloons. The data gathered will support a premarket notification for the Peripheral AVE Biliary Stent System.

   Results:
   The test proved substantial equivalence.

2. **Peripheral AVE Biliary Stent System vs JJIS Palmaz™ Balloon-Expandable Stent – Two Plane Crush Strength Study**

   Purpose:
   To determine and compare the radial strengths of the Peripheral AVE Biliary Stent and the PALMAZ™ Balloon-Expandable Stent by graphically representing the amount of force required to crush a stent to fifty percent (50%) of its deployed diameter. The data gathered will support a premarket notification for the Peripheral AVE Biliary Stent System.

   Results:
   The test proved substantial equivalence.

3. **Peripheral AVE Biliary Stent Dimensional Verification and Stent Uniformity at Nominal Deployment**

   Purpose:
   To verify that processed Peripheral AVE Biliary Stents meet diameter and length specifications after deployment. The data gathered will support a premarket notification for the Peripheral AVE Biliary Stent System.

   Results:
   The results conclude that the stents tested meet the labeled specifications for stent diameter and stent length.

CONCLUSIONS:

The Peripheral AVE Biliary Stent vs the JJIS Palmaz™ Balloon-Expandable Stent performance testing results prove that the Peripheral AVE Biliary Stent is substantially equivalent to the JJIS Palmaz™ Balloon-Expandable Stent

Additional Information:

Per 807.92(d), the summary includes any other information reasonably deemed necessary by FDA.

BIOCOMPATIBILITY

The materials employed in the Peripheral AVE Biliary Stent Delivery System passed all biocompatibility tests.

STERILIZATION INFORMATION

The Peripheral AVE Biliary Stent System is provided sterile.

The Peripheral AVE Biliary Stent System is not intended for sterilization or reuse/ resterilization by the user.

Validation

Peripheral AVE validates the sterilization method, for its stent delivery system products, quarterly each year according to the ANSI/ AAMI/ ISO 11137 - 1994, Method I. Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization.

Sterility Assurance Level (SAL)

The Sterility Assurance Level or SAL for the validated AVE stent systems is 10^{-6}.

Pyrogen Testing

The Peripheral AVE Biliary Stent System is labeled "pyrogen free". LAL testing is performed daily, in compliance with FDA guideline 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 Peripheral AVE's product release criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Mr. Paul A. Meyer
RA/QA/CA Manager
Peripheral AVE
2330A Circadian Way
Santa Rosa, California 95407

Re: K983008
Peripheral AVE Biliary Stent System
Regulatory Class: II
21 CFR §876.5010
Product Code: 78 FGE
Dated: August 27, 1998
Received: August 28, 1998

Dear Mr. Meyer:

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 predicte 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): K983008

Device Name: Peripheral AVE Biliary Stent System

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

The Peripheral AVE Biliary Stent System is intended to maintain patency of biliary duct which is occluded by a malignant tumor.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983008

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