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AVE Bridge™ 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: K971295

GENERAL INFORMATION

Applicant:

Date: 2 April, 1997
 Name: Arterial Vascular Engineering, Incorporated
 Address: 3576 Unocal Place
 Santa Rosa, CA 95403
 Contact: Joseph Tamayo
 Phone Number: (707) 525-0111
 FAX Number: (707) 525-0114

Trade Name:

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

Section 513 Device Classification:

Classification: Class II
 Classification Panel: 78FGE

EQUIVALENCE

Arterial Vascular Engineering, Incorporated, claims substantial equivalence to the Johnson & Johnson Interventional Systems' PALMAZ™ Balloon-Expandable Stent.

INTENDED USE

The Arterial Vascular Engineering, Incorporated (AVE) Bridge™ Stent System is intended for use in patients to maintain patency of a biliary duct which is occluded by tumor.

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

This device is not intended for intravascular use.

DEVICE DESCRIPTION

The AVE Bridge™ Stent System consists of a balloon-expandable intraluminal stent premounted onto the balloon of an over-the-wire delivery catheter. The AVE Bridge™ 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 AVE Bridge™ Stent System is provided enclosed in a sterile package.

Size Range:

Diameters - 6.0 mm to 10.0 mm

Lengths - 16 mm to 40 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:	<p>The AVE Bridge™ Stent System is intended for use in patients to maintain patency of a biliary duct which is occluded by tumor.</p> <p>The AVE Bridge™ Stent System is indicated for palliative treatment of biliary duct strictures caused by malignant tumors.</p>	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):	<p>316L stainless steel balloon expandable stent - premounted</p> <ul style="list-style-type: none"> • Diameters - 6 mm to 10 mm • Lengths - 16 mm to 40 mm 	<p>316L stainless steel balloon expandable stent - premounted or unmounted</p> <ul style="list-style-type: none"> • Diameters - 4 mm to 12 mm • Lengths - 9 mm to 40 mm
Physical Characteristics (Delivery catheter):	<p>balloon delivery system - PTA catheter</p> <ul style="list-style-type: none"> • 5.3 F shaft size • 75 cm to 90 cm length • 0.035 in. Guidewire diameter 	<p>balloon delivery system - PTA catheter</p> <ul style="list-style-type: none"> • 5 F to 7 F shaft size • 75 cm length • 0.035 in. Guidewire diameter <p>for unmounted stents - Medi-tech PE-MT™ PTA balloon catheters</p> <ul style="list-style-type: none"> • 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. AVE Bridge™ Stent vs JJIS Palmaz™ Balloon-Expandable Stent – Balloon Performance Study

Purpose:

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

Results:

The test proved substantial equivalence.

2. AVE Bridge™ Stent vs JJIS Palmaz™ Balloon-Expandable Stent – Two Plane Crush Strength Study

Purpose:

To determine and compare the radial strengths of the AVE Bridge™ 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 AVE Bridge™ Stent System.

Results:

The test proved substantial equivalence.

3. AVE Bridge™ Stent Dimensional Verification and Stent Uniformity at Nominal Deployment

Purpose:

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

Results:

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

CONCLUSIONS:

The AVE Bridge™ Stent vs the JJIS Palmaz™ Balloon-Expandable Stent performance testing results prove that the AVE Bridge™ 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 AVE Bridge™ Stent Delivery System passed all biocompatibility tests.

STERILIZATION INFORMATION

The AVE Bridge™ Stent System is provided sterile.

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

Validation

Arterial Vascular Engineering, Incorporated 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 AVE Bridge™ 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 AVE's product release criteria.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Joseph Tamayo
Regulatory Affairs Specialist
Arterial Vascular Engineering, Inc.
3576 Unocal Place
Santa Rosa, California 95403

Re: K971295
AVE Bridge™ Stent System
Dated: August 12, 1997
Received: August 13, 1997
Regulatory class: II
21 CFR §876.5010/Product code: 78 FGE

Dear Mr. Tamayo:

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 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 requirement, 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.

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) 594-4613. 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/dsmamain.html>.

Sincerely yours,

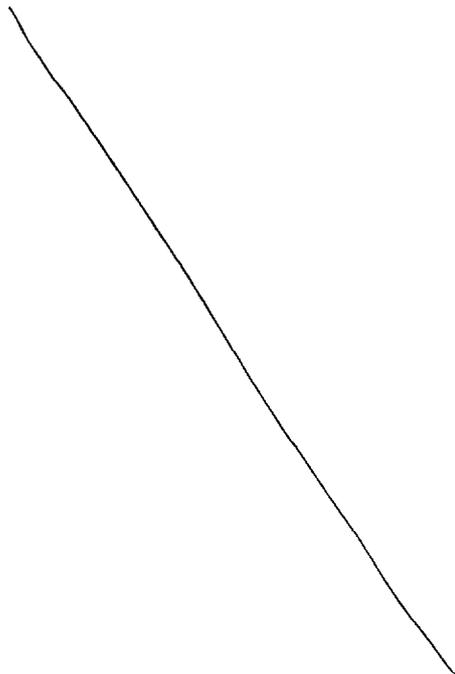
Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number: K971295
Device Name: AVE Bridge™ Stent System

Indications For Use:

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



(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Robert E. Natting
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971295