FEB - 4 2004

XIII. 510(k) Summary

K032436

510(k) Summary - DuraMax™.018 Biliary Stent System

Submitter	Avantec Vascular Corporation 1049 Kiel Court Sunnyvale, CA 04089
Date Prepared	August 4, 2003
Contact Person	James M. Shy Phone: (408) 743-3125 FAX: (408) 548-0088 e-mail: jshy@avantecvascular.com
Classification Name	21 CFR 876.5010 Biliary Catheter and accessories
Device Common Name	Biliary Stent System
Device Trade Name	DuraMax™.018 Biliary Stent System
Intended Use	The DuraMax™ .018 Biliary Stent System is indicated for palliation of malignant neoplasms in the biliary tree
Device Classification	Regulatory Class: Class II (two) Product Code: FGE
Predicate Device	Cordis® PALMAZ® GENESIS™ Transhepatic Biliary Stent on SLALOM .018" Delivery System.
Performance Standards	Have not been established for this device.
Device Description	The DuraMax™ .018 Biliary Stent Delivery System is a balloon-expandable 316L stainless steel stent pre-mounted on a delivery catheter. The delivery catheter is an Over-the-Wire (OTW) design with a distal balloon and two radiopaque markers to aid in the placement of the stent. The proximal end of the catheter has a Y-connector that allows for the use of a guidewire ≤0.018" and the attachment of a balloon inflation device via a standard luer connector. Stents sizes include diameters of 5, 6 & 7 mm in lengths of 13, and 18 mm. The catheter is available in two working lengths, 80 cm and 135 cm. Shaft markers at 93 and 103 cm are provided on the 135 cm catheter. The catheter system is provided sterile and is intended for one use only.
Biocompatibility	The DuraMax™ .018 Biliary Stent System has passed all Biocompatibility testing.
Performance Data	The safety and effectiveness of the DuraMax™.018 Biliary Stent Delivery System have been demonstrated with data collected form non-clinical design verification tests and analyses.
Summary	The DuraMax™ .018 Biliary Stent System is constructed of similar materials, is available in similar diameters and lengths, has a similar design and the same indications as the Predicate Device and other currently marketed Biliary Stent Systems. Bench and Biocompatibility testing has demonstrated the safety and effectiveness of the device.
Conclusion	The DuraMax™ .018 Biliary Stent System is substantially equivalent to the predicate device and other currently marketed Biliary Stent Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James M. Shy
Vice President, Regulatory Affairs
Avantec Vascular Corporation
1049 Kiel Court
SUNNYVALE CA 94089

FEB 4 - 2004

Re: K032436
Trade/Device Name: DuraMax™ .018 Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: November 21, 2003
Received: November 24, 2003

Dear Mr. Shy:

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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Section 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 Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032436

Device Name: DuraMax™ .018 Biliary Stent System

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

The DuraMax™ .018 Biliary Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032436