

DEC 30 1999

16. 510(k) Summary

Date Prepared

September 24, 1999

Submitter

Address: Boston Scientific Corporation
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Minneapolis, MN 55442

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Contact Person

Ronald W. Bennett
Regulatory Affairs Project Manager

Device Name and Classification

Trade Name WALLSTENT® Biliary Endoprosthesis
with Unistep™ Plus Delivery System

Common Name Biliary Stent

Classification Class II

Predicate Devices

WALLSTENT® Biliary Endoprosthesis
with Unistep™ Plus Delivery System - K964119

Device Description

The WALLSTENT® Biliary Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. Smaller diameter models may utilize a radiopaque core. The prosthesis is a braided wire structure that may be covered with an elastomeric polymer in selected models. The outward radial force along with the ends of the device serve to stabilize the prosthesis after implanted. The stent's purpose is to increase or maintain the inner lumen diameter of the biliary duct.

The stent is placed by means of a delivery system. The delivery system is a coaxial tubing assembly that constrains the prosthesis until it is released in a controlled manner. The release of the stent is accomplished by retracting the outer sheath. The prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only.

Indication

The WALLSTENT® Biliary Endoprosthesis is intended for use in the treatment of biliary strictures produced by malignant neoplasms.

Technological Characteristics

The purpose of this 510(k) is to allow an alternate delivery system. Compared to the present Unistep™ Plus Delivery System (K964119), this version of the Unistep™ Plus delivery system has a reduced profile, that is smaller French size.

The alternate delivery system can be found substantially equivalent based on the results of *in vitro* testing that demonstrates the deployment forces and handling characteristics are comparable to the current delivery systems.

Summary

In summary Boston Scientific Corporation has demonstrated that the WALLSTENT® Biliary Endoprosthesis with Unistep™ Plus Delivery with reduced profile for the delivery system is substantially equivalent based on design, test results, and indications for use to the predicate devices.



DEC 30 1999

Mr. Ronald W. Bennett
Regulatory Affairs Project Manager
Plymouth Technology Center
Boston Scientific Corporation
5905 Nathan Lane
Plymouth, MN 55442

Re: K993232
Wallstent® Biliary Endoprosthesis
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: September 24, 1999
Received: September 27, 1999

Dear Mr. Bennett:

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.

Page 2 – Mr. Ronald W. Bennett

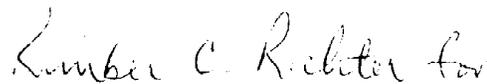
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



David W. Feigal, Jr., M.D., M.P.H.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

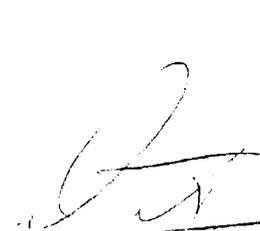
Enclosure

510(k) Number (if known): K993232

Device Name: Wallstent® Biliary Endoprosthesis

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

The Wallstent® Biliary Endoprosthesis is indicated for the palliation of malignant neoplasms in the biliary tree.



(Division of Neurological, Abdominal, ENT,
Division of Neurological, Abdominal, ENT,
and Radiological Devices
510(k) Number _____

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