K982005

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SEP 2 1998

16. 510(k) Summary

Date Prepared June 4, 1998

Submitter

Address: Schneider (USA) Inc
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Minneapolis, MN 55442

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Contact Person

Ronald W. Bennett
Senior Regulatory Affairs Specialist

Device Name and Classification

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

Common Name: Biliary Stent

Classification: Class II

Predicate Devices WALLSTENT® Biliary Transhepatic Endoprosthesis with Unistep™ Plus Delivery System – K923993, K961262, K964119

Device Description

The WALLSTENT® Biliary Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. The prosthesis is a braided wire structure. 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 Unistep™ Delivery System (K961262, K923993), the Unistep™ Plus delivery system allows the user to partially deploy and then reconstrain the stent to facilitate placement. Compared to the present Unistep™ Plus Delivery System (K964119), the modified system has different materials for the outer and inner tubing. This feature is presently available for the 12 mm stent with the change in materials in the WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System (K980163).

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

Summary
In summary Schneider (USA) Inc has demonstrated that the WALLSTENT® Biliary Endoprosthesis with Unistep™ Plus Delivery System with modified delivery system is substantially equivalent based on design, test results, and indications for use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1998

Mr. Ronald W. Bennett
Senior Regulatory Affairs Specialist
Schneider (USA) Inc.
Pfizer Medical Technology Group
5905 Nathan Lane
Minneapolis, MN 55442

Re: K982005
WALLSTENT® with Unistep™ Plus (Biliary Stent and Catheter)
Dated: June 4, 1998
Received: June 8, 1998
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

Dear Mr. Bennett:

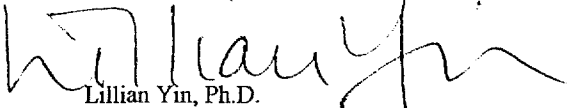
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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/dsma/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 (if known):

Device Name: **Schneider WALLSTENT® Biliary Endoprosthesis**

Indications for Use:

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

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982005