K991056

JUN 2 2 1999

510(k) Summary
for
The WALLSTENT® Enteral Endoprosthesis

Date Prepared: March 29, 1999

Sponsor: Boston Scientific Corporation
5905 Nathan Lane
Plymouth, MN 55442
Phone: (612)550-5500

Contact: Daniel J. Dillon
(508)-650-8751

Device Proprietary Name: WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System

Classification: Class III

Equivalent Devices: WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System, K954290 and K980113

Device Description:

The WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System is composed of two components: the implantable metallic stent and the delivery device. The stent is composed of implant-grade cobalt-base superalloy wire braided in a tubular mesh configuration. The design configuration results in a stent that is flexible, compliant, and self-expanding. The stent is available in multiple sizes. Physician preference and individual patient condition and/or anatomy will determine the appropriate size chosen.

Intended Use:

This device is intended for palliative treatment of colonic, duodenal or gastric outlet obstruction or strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures. It is physically identical to the predicate WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System, which is indicated for palliative treatment of colonic and duodenal strictures produced by malignant neoplasms. The device described in this submission differs only in the additional indication.

Technological Characteristics:

The WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System has technological (materials, construction, processing) characteristics identical to those of the

predicate WALLSTENT® device. These devices allow for self expanding deployment using dynamic radial force to gently and firmly expand the lumen diameter. The WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System will be used to open a pathway through a restricted lumen. The predicate devices achieve the same end result.

A search of clinical literature has found that the clinical *in vivo* experience of a stent within the clinical indication that we are requesting has been successful. In brief a metal stent placement within the obstructed colon permits definitive surgery to be postponed until it can be performed in a better prepared patient.

Performance testing was done on predicate devices. Tests included fatigue, corrosion resistance, relative radial force, and stent deformation testing to assure mechanical strength of the wire. The results were all within the expected ranges. Because this is a request for an additional indication and introduces no new materials, designs, or processes, these tests were not repeated.

The results of the literature search and tests demonstrate that the WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System is equivalent to the predicate device and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 1999

Mr. Daniel J. Dillon
Regulatory Affairs Project Manager
Boston Scientific Corporation
Microvasive Endoscopy
One Boston Scientific Place
Natick, MA 01760-1537

Re: K991056
WALLSTENT® Enteral Endoprosthesis
with Unistep™ Delivery System
Dated: March 29, 1999
Received: March 30, 1999
Regulatory Class: III
21 CFR §878.3610/Procode: 78 MQR

Dear Mr. Dillon:

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. 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K99/056

Device Name: **WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System**

Indication for Use:

The WALLSTENT® Enteral Endoprosthesis with Unistep™ Delivery System is indicated for palliative treatment of colonic, duodenal or gastric outlet obstruction or strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

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)

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K99/056