

510(k) Summary  
for  
The WALLSTENT® Enteral Endoprosthesis

APR - 3 1998

**Date Prepared:** January 12, 1998

**Sponsor:** Schneider (USA) Inc  
5905 Nathan Lane  
Plymouth, MN 55442  
Phone: (612)550-5500

**Contact:** Kathy Jo Fahey  
Sr. Regulatory Affairs Specialist  
(612)550-5623

**Device Proprietary Name:** WALLSTENT® Enteral Endoprosthesis

**Classification:** Class III

**Equivalent Devices:** WALLSTENT® Enteral Endoprosthesis

**Device Description:**

The WALLSTENT® Enteral Endoprosthesis is comprised of two components: the temporary (short-term) 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 as a for the palliative treatment of duodenal strictures caused by malignant neoplasms. This device is intended as a non-surgical permanent implant as a safe and effective procedure to eliminate gastric outlet obstruction.

**Technological Characteristics:**

The WALLSTENT Enteral Endoprosthesis has identical technological (materials, construction, processing) characteristics as the predicate device the WALLSTENT® devices. These devices allow for self expanding deployment using dynamic radial force to gently and firmly expand the lumen diameter. The WALLSTENT® Enteral Endoprosthesis will be used to open a pathway through a restricted lumen. The other predicate devices ultimately 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 duodenal area has been successful in the decompression of a stricture, allowing for immediate relief of gastric outlet obstruction and permitting the patient oral intake of nutrients within several hours to days of the procedure. This procedure eliminates the need for surgical bypass.

Performance testing was done on the predicate device. 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, design or processes these tests were not repeated.

The results of these tests demonstrate that the Schneider WALLSTENT® Enteral Endoprosthesis is equivalent to the predicate device and is therefore safe for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 3 1998

Ms. Kathy Jo Fahey  
Senior Regulatory Affairs Specialist  
Schneider, (USA), Inc.  
5905 Nathan Lane  
Minneapolis, MN 55442

Re: K980113  
WALLSTENT® Enteral Endoprosthesis and  
UNISTEP™ Delivery System  
Dated: January 12, 1998  
Received: January 13, 1998  
Regulatory Class: III  
21 CFR 878.3610/Procode: 78 MUM

Dear Ms. Fahey:

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® Enteral Endoprosthesis**

Indication for Use:

**The Schneider (USA) Inc Enteral Endoprosthesis is indicated for palliation of duodenal strictures caused by malignant neoplasms.**

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Sattling  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K980113

Prescription Use  or  
(Per 21 CFR 801.109)

Over-The-Counter Use \_\_\_\_\_