

K 984068

JAN 7 1999

510(k) Summary

Flamingo™ WALLSTENT® Esophageal Endoprosthesis

General Information

Date Prepared: November 11, 1998

Classification: Class III

Trade Name: Flamingo™ WALLSTENT® Esophageal Endoprosthesis

Submitter: Schneider (Europe) GmbH
Ackerstrasse 6, CH-8180 Bülach, Switzerland
Tel. ++41 872 11 11; Telefax ++41 862 05 04

Contact: Thomas Thaler, Ph. D.
Director, Clinical and Regulatory Affairs

Predicate Device: WALLSTENT® Esophageal Prosthesis, K940396 and K923119

Device Description:

The Flamingo™ WALLSTENT® Esophageal Endoprosthesis is a self expanding prosthesis constructed of biomedical superalloy with an elastomeric polymer covering. The prosthesis is a braided wire structure which is covered with elastomeric polymer over approx. 75 % of it's length. The outward radial force, the conical shape of the stent along with the ends of the device serve to stabilize the prosthesis when placed. The stent's purpose is to increase or maintain the inner luminal diameter of the esophageal passage or to close tracheo-esophageal fistulae.

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

In summary, Schneider (Europe) GmbH believes the above listed predicate devices and the Flamingo™ WALLSTENT® Esophageal Endoprosthesis are substantially equivalent based on design, materials, methods of fabrication and indications for use.



JAN 7 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Thomas Thaler, Ph.D
Director, Clinical and Regulatory Affairs
Schneider (Europe) GmbH
Ackerstrasse 6, P.O. Box
CH-8180 Bülach, Switzerland

Re: K984068
Trade Name: Flamingo Wallstent Esophageal Endoprosthesis
Regulatory Class: III
Product Code: ESW
Dated: November 12, 1998
Received: November 16, 1998

Dear Dr. Thaler:

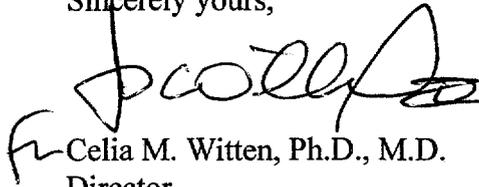
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and includes a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K984068

Premarket Notification for the
Flamingo™ WALLSTENT®
Esophageal Endoprosthesis

510(k) number (if known):

Device name: **Flamingo™ WALLSTENT® Esophageal Endoprosthesis**

Indications for Use: **The Flamingo™ WALLSTENT® Esophageal Endoprosthesis is intended to be used for the**
- palliative treatment of strictures of the esophagus, including cardia, due to a malignant process
- palliative treatment of tracheo-esophageal fistulae due to a malignant process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X
Prescription

OTC

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984068