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510(k) Summary
for
The WALLSTENT® Enteral Endoprosthesis

JUL 10

JUL 10 1996

Date Prepared: May 15, 1996

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

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

Device Proprietary Name: WALLSTENT® Enteral Endoprosthesis

Classification: Class III

Equivalent Devices: WALLSTENT® Esophageal Prosthesis

Device Description:

The WALLSTENT® Enteral Endoprosthesis is comprised 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:

The Schneider WALLSTENT® Enteral Endoprosthesis is indicated for the palliative treatment of colonic strictures produced by malignant neoplasms.

Technological Characteristics:

The WALLSTENT® Enteral Endoprosthesis has identical technological (materials, construction, processing) characteristics as the predicate devices 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 enteral area has been successful in opening a bowel obstruction to allow for passage of the bowel's contents, relieving abdominal distention and discomfort.

Performance testing was done on the predicate devices. Tests included fatigue and radial force testing to assure mechanical strength of the wire. The results were all within the expected ranges. Because the WALLSTENT® Enteral Endoprosthesis introduces no new materials, design or processes of 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.