

K961262

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510(k) SUMMARY

General Information

Date Prepared March 29, 1996

Classification Class II

Trade Name WALLSTENT® Biliary Transhepatic Endoprosthesis
WALLSTENT® Biliary Endoscopic Endoprosthesis

Common Name Biliary Stent

Submitter Schneider (USA) Inc
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Predicate Device WALLSTENT® Biliary Transhepatic Endoprosthesis
WALLSTENT® Biliary Endoscopic Endoprosthesis
K911292, K914277, K923993

K961262

Device Description

The WALLSTENT® Biliary Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy with a radiopaque core. The prosthesis is a braided wire structure allows for self expansion. This premarket notification deals with the modification of the 12 mm diameter prosthesis to increase the radial force.

The delivery system is a coaxial tubing assembly which constrains the prosthesis until it is released in a controlled manner. The release of the prosthesis is accomplished by pulling the outer tube back, thus exposing the stent and allowing gradual release and expansion of the prosthesis. The prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only. The fully expanded stents are offered in sizes from 8 to 12 mm.

Intended Use

The indication for the use of the WALLSTENT® Endoprosthesis is "for treatment of biliary strictures produced by malignant neoplasms."

Technological Changes

This premarket notification deals with the modification of the 12 mm diameter prosthesis to standardize the relative radial force. This is accomplished by increased wire diameter and the number of wires used to fabricate the stent.

The modified 12 mm diameter stent can be found substantially equivalent based on the results of axial fatigue and relative radial force testing which demonstrate that the fatigue life and relative radial force are comparable to the predicate device.

Summary

In summary Schneider (USA) Inc believes the modified device is substantially equivalent based design, materials, methods of fabrication and indications for use.