

APR 28 1997

K964119

16. 510(k) SUMMARY

General Information

Date Prepared September 26, 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, K914227, K923993, K961262

Device Description

The WALLSTENT® Biliary Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. The prosthesis is a braided wire structure. The outward radial force along with the ends of the device serve to stabilize the prosthesis after implanted. The stent's purpose is to increase or maintain the inner luminal diameter of the biliary duct.

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 retracting the outer sheath. The prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only.

Indication

The WALLSTENT® Biliary Endoprosthesis is intended for use in the treatment of biliary strictures produced by malignant neoplasms.

Technological Characteristics

The purpose of this 510(k) is to allow an alternate delivery system which allows the user to partially deploy and then reconstrain the stent to facilitate placement. This feature is presently available in the Esophageal delivery system (K940396).

The alternate delivery system can be found substantially equivalent based on the results of *in vitro* and *in vivo* deployment testing which demonstrate that deployment forces and handling characteristics are comparable to the current delivery system.

Summary

In summary Schneider (USA) Inc believes the alternate delivery system is substantially equivalent based on design, test results, and indications for use.