K955728
0-000047

SUMMARY OF SAFETY AND EFFECTIVENESS

MAY -8 1996

I. General Provisions

Common or Usual Name: Biliary Stents

Proprietary Name: Cordis Biliary Stent

II. Name of Predicate Devices

1. Johnson & Johnson Interventional Systems Palmaz™ Balloon Expandable Stent (K905720 and K911581) for design and intended use.

2. Schneider Wallstent® Transhepatic Biliary Endoprosthesis (K885180, K896163, K911292, K914277) for intended use and design.

3. Cook Incorporated Gianturco-Rosch Biliary Z Stents™ (K921191, K903858, K882610) for intended use and design.

III. Classification

Class II, 21CFR 876.5010, Biliary Catheters and Accessories.

IV. Performance Standards

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Cordis Biliary Stent intended use is to maintain patency of a bile duct which is obstructed from malignant neoplasms.

The Cordis Biliary Stent is a helical coil made of flexible radiopaque 5400 Grade Tantalum (Ta). The stent is available in 7.0 mm diameter size. The nominal expanded length of the stent is 1.5 cm and 3.0 cm. The stent is supplied mounted and crimped onto a balloon catheter delivery system, the size of which determines the delivered diameter of the stent.

VI. Biocompatibility

All appropriate biocompatibility tests as specified by ISO 10993 Part 1 - Biological Evaluation of Medical Devices, were successfully performed on the Cordis Biliary Stent.

VII. Summary of Substantial Equivalence

The Cordis Biliary Stent is similar in its basic design, construction, indication for use and performance characteristics to other commercially available biliary stents. *In-vitro* and *in-vivo* testing was conducted to support substantial equivalence to the predicate devices.