C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209

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BARD

SECTION VI

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter's Name: C. R. Bard, Inc., Radiology Division
Submitter's Address: 13183 Harland Drive., Covington, GA 30209
Contact Person: Donna J. Wilson
Contact Person's Address: 8195 Industrial Blvd.,
Covington, GA 30209
Contact Person's Telephone Number: 770-784-6135
Contact Person's FAX Number 770-784-6419
Date of Preparation: September 16, 1996

B. Device Name:

Bard® Memotherm® Transhepatic Biliary Endoprosthesis

C. Predicate Device Name:

Schneider Wallstent

D. Device Description

The Bard Memotherm Transhepatic Endoprosthesis is a stenting device designed to maintain the patency of biliary ducts obstructed by malignant neoplasms. The device includes the self-expanding Bard Memotherm Transhepatic Biliary Endoprosthesis pre-loaded on a unique delivery system. This 7 Fr. delivery system is compatible with a 7 Fr. introducer and accepts a .035" guidewire. The Bard Memotherm Transhepatic Biliary Endoprosthesis is available in various diameters and lengths.

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E. Intended Use:

The Bard Memotherm Transhepatic Biliary Endoprosthesis is indicated for use in the treatment of biliary strictures resulting from malignant neoplasms.

F. Technological Characteristics Summary:

The Bard Memotherm Transhepatic Biliary Endoprosthesis is a metal mesh stent constructed of biocompatible nitinol. It is self-expanding and is packaged pre-mounted on a disposable delivery system. It will be available in expanded diameters of 7, 8, 9, 10 and 12mm and in lengths from 30mm to 110mm.

G. Performance Data:

The Bard Memotherm Transhepatic Biliary Endoprosthesis deploys easily from the delivery system even in a tortuous path. The delivery system withstands pull test forces in excess of 5 lbs for the shaft-to-handle joint and in excess of 2 lbs for the tip-to-shaft joint. Elastic properties of the Memotherm stent are comparable to those for the predicate device. The stent is resistant to corrosion by bile and to compressive forces expected to be encountered within the biliary system.