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Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

BARD

VI 510(k) SUMMARY SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

A. Submitter Information

Submitter's Name:	Bard Interventional Products Division
	C.R. Bard, Inc.
Address:	129 Concord Road, Bldg. #3
	Billerica, MA 01821
Phone:	978 – 262 – 4867
Fax:	978 – 262 – 4878
Contact Person:	Marion Gordon, R.A.C.
Date of Preparation:	December 11, 1998

B. Device Name

Trade Name:	Memotherm® Colorectal Stent
Common/Usual Name:	Expandable, metallic colonic stent
Classification Name:	FDA has not classified to date

C. Predicate Device Name

Trade Name:	WALLSTENT® Enteral Endoprosthesis
	Schneider (USA), Inc.

D. Device Description:

The Memotherm® Colorectal Stent comprised of two components – a self-expanding implantable metal stent and the delivery device. The stent is a nitinol grid-like cylinder with flared ends, available in ~~20~~ 25 and 30mm

diameters and 60, 80, and 100mm lengths. While mounted on the deployment system the stent is compressed. Upon release of the stent from the deployment system the nitinol cylinder expands. The coaxial deployment system consists of an inner catheter, an outer sheath and an ergonomically shaped handgrip. Female luer injection ports are included on the back of the handgrip and ratchet carriage. Two radiopaque markers are positioned on the deployment system to mark both ends of the stent.

E. Intended Use:

The proposed stent is indicated for the palliative treatment of colonic strictures and obstruction caused by malignant neoplasms in the rectum, sigmoid colon and descending colon.

F. Technological Characteristics Summary:

The Memotherm® Colorectal Stent is a metal stent constructed of biocompatible nitinol. The self-expanding stent is packaged pre-mounted on a disposable delivery system that utilizes an uni-directional, pistol grip handle release mechanism.

The Memotherm® Colorectal Stent is substantially equivalent to the Schneider WALLSTENT® Enteral Endoprosthesis. Both devices are manufactured with a delivery system that implants a self-expanding metal stent over a guidewire using a coaxial, interfacing catheter/sheath (tubes). While each manufacturer's metal stents are made from different materials, both allow for self-expanding deployment using radial force to expand the inner colon lumen. The WALLSTENT can be placed via the colonoscope's working channel, while the Memotherm is positioned using fluoroscopy after the guidewire has been inserted using the colonoscope. Both manufacturers have the same intended use for the device and have stents within the same range of diameters and lengths.

G. Performance Data

Safe and effective *in vivo* use of self-expanding, metal stents in the colon

has been demonstrated in relevant published, scientific, literature. Metal stents have been shown to be effective, in palliative treatment of colon cancers, and give the patients relief from partial or complete obstructions caused by the disease.

Comparative performance testing was done, where appropriate, between the Memotherm and WALLSTENT. In addition to testing various tensile and dimensional verifications, other bench data included trackability, deployment and stent expansion/compression were completed. The stent is resistant to corrosion within the intended anatomical environment based on Bard's experience with other metal stents. All data was within the anticipated results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Marion Gordon, R.A.C.
Senior Regulatory Affairs Coordinator
Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road, Bldg. #3
P.O. Box 7031
Billerica, MA 01821-7031

Re: K990504
Memotherm® Colorectal Stent
Dated: October 8, 1999
Received: October 12, 1999
Regulatory Class: III
21 CFR 878.3610/Procode: 78 MQR

Dear Ms. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990504

510(k) Number (if known): TBD K990504

Device Name: Memotherm® Colorectal Stent

Indications For Use: The Memotherm® colorectal stent is indicated for the palliative treatment of colonic strictures and obstruction caused by malignant neoplasms in the rectum, sigmoid colon and descending colon.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990504/S002

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