Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road, Bldg #3
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

JAN - 6 2000

BARD

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:	November 15, 1999

B. Device Name

Trade Name:	DURAglide^{3} ™ Stone Balloon
Common/Usual Name:	Biliary Catheter
Classification Name:	Class II, 21 CFR 876.5010, 78FGE

C. Predicate Device Name:	Stone Removal Balloon Catheter
	K920342
Trade Name:	DURAglide™ Stone Balloon

D. Description:

The DURAglide^{3} ™ Stone Balloon is a sterile, single patient use, triple lumen stone removal balloon catheter.

E. Intended Use:

The proposed stone balloon is intended for removal of biliary stones from the common bile duct.

F. Technological Characteristics Summary:

The DURAglide^{3} ™ is a three-lumen line extension to our two-lumen stone removal balloon. The proposed device has the same intended use and fundamental scientific technology.

G. Performance Standards

The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards for the proposed device. All materials used in the Duraglide3™ Stone Balloon are biocompatible.

Design control, risk analysis and design verification activities for the proposed device have been conducted in accordance with internal procedures and inclusive of the elements stipulated by 21 CFR 820.30, as applicable to this device. All results obtained during design verification activities met our predetermined acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2000

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: K993892
DURAglide3™ Stone Removal Balloon Catheter
(three-lumen)
Dated: December 9, 1999
Received: December 10, 1999
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

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

510(k) Number (if known): TBD K993892

Device Name: DURAglide^{3} ™ Stone Balloon

Indications For Use: For removal of biliary stones from the common bile duct.

(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 K993892 | S001