

Bard Interventional Products Division  
C.R. Bard, Inc.  
129 Concord Road  
P.O. Box 7031  
Billerica, MA 01821-7031  
508-663-8989

K971137

**BARD**

OCT 16 1997

6.0 510(k) SUMMARY FOR THE BARD® RAPIDFIRE™ MULTIPLE BAND LIGATOR

As required under Section 12, part (a)(1)(3A) of the Safe Medical Device Act of 1990, an adequate summary of any information respecting the safety and effectiveness follows.

6.1 General Information

• Name and Address of Submitter:

Bard Interventional Products Division, C.R. Bard, Inc.  
129 Concord Road, Building #3  
Billerica, MA 01821-7031

• Contact:

Beth A. Rochette  
Regulatory Affairs Manager  
Phone: (508) 663-8989  
Fax: (508) 670-9827

• Date of Summary:

February 25, 1997

• Name of Device:

Trade Name:	Bard® RapidFire™ Multiple Band Ligator
Common/Usual Name:	Esophageal Variceal Ligator/Hemorrhoidal Ligator
Classification Name:	Esophageal Variceal Ligator/21 CFR 876.440/ 78 MND Hemorrhoidal Ligator/21 CFR 876.440/78 FHN

• Predicate Device(s):

Microvasive® Speedband™ Multiple Band Ligator and Bard Stiegmann-Goff™ Endoscopic Ligator

• Description and Intended Use:

The RapidFire Multiple Band Ligator is indicated for use in endoscopic ligation of esophageal varices and anorectal hemorrhoids.

## 6.2 Summary of Similarities and Differences

The Bard RapidFire Multiple Band Ligator is substantially equivalent to the currently marketed Microvasive Speedband Multiple Band Ligator (K952262) manufactured by Microvasive, Boston Scientific Corporation and the Stiegmann-Goff Endoscopic Ligator manufactured by Bard® Interventional Products Division which received concurrence through K940661.

The indications for use of the RapidFire™ Multiple Band Ligator are equivalent to both the Microvasive® Speedband™ Ligator and the Stiegmann-Goff™ Endoscopic Ligator. The general design, materials and functionality of the RapidFire Multiple Band Ligator is equivalent to the Microvasive Speedband Ligator. All of the ligators are attached to the endoscope prior to introduction into the esophagus or rectum. The firing system of the RapidFire Ligator and the Microvasive Speedband Ligator include a spool with crank-trip wire filament. The dimensions of the RapidFire Multiple Band Ligator assemblies and bands are nearly identical to the Microvasive Speedband Ligator and both units use a single size scope adapter. The major differences are listed below:

1. The RapidFire Multiple Band Ligator contains either five or eight ligating bands per ligating unit while the Microvasive ligator contains five ligating bands and the Bard Stiegmann-Goff Ligator contains one ligating band per cylinder, with five or ten cylinders per package.
2. The RapidFire Ligator and the Microvasive Speedband Ligator do not use an overtube during the procedure, whereas, the Stiegmann-Goff Endoscopic Ligator recommends the use of an overtube for multiple intubations

The materials used in the RapidFire Multiple Band Ligator and the Microvasive Speedband Ligator units are nearly identical and are all commonly used in the medical device industry, however, biocompatibility testing will be completed to confirm that the different vendor materials used in the RapidFire Multiple Band Ligator are safe for limited and prolonged contact with mucosa and tissue.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 16 1997

Ms. Beth Zis  
Regulatory Affairs Manager  
C.R. Bard, Inc.  
Bard Interventional Products Division  
129 Concord Road  
P.O. Box 7031  
Billerica, Massachusetts 01821-7031

Re: K971137  
Bard RapidFire Multiple Band Ligator  
Dated: July 21, 1997  
Received: July 22, 1997  
Regulatory class: II  
21 CFR §876.4400/Product code: 78 MND and FHN

Dear Ms. Zis:

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 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 requirement, 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/dsmamain.html>.

Sincerely yours,

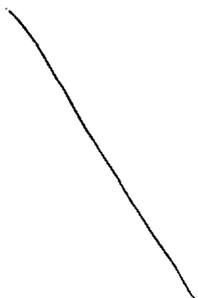
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): Not Known

Device Name: Bard® RapidFire™ Multiple Band Ligator

Indications for Use: The RapidFire™ Multiple Band Ligator is used for endoscopic ligation of esophageal varices and anorectal hemorrhoids.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Smith  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K971137

Prescription Use  OR  
(Per 21 CFR 801.109)

Over-the-Counter Use

(Optional Format 1-2-96)