DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

C. R. Bard, Inc.
Bard Interventional Products Division
Ms. Beth A. Zis
Regulatory Affairs Manager
129 Concord Road, Building #3
P.O. Box 7031
Billerica, MA 01821-7031

JUL 27 2015

Re: K994290
Trade/Device Name: Endoscopic Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated (Date on orig SE ltr): December 20, 1999
Received (Date on orig SE ltr): December 21, 1999

Dear Ms. Zis,

This letter corrects our substantially equivalent letter of March 20, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K994290

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

Device Name: Bard® Endoscopic Suturing System

Indications for Use: For endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic Gastroesophageal Reflux Disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

NRO for CDRH

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994290

K994290 (P.1 of 3)

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BARD

VI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required under Section 513(i)(3)(A) of the Safe Medical Device Act of 1990, an adequate summary of any information respecting the safety and effectiveness follows:

A. 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. Zis, R.A.C. Manager of Regulatory Affairs Phone: (978) 262-4866 Fax: (978) 262-4878
Date of Summary:	December 6, 1999
Name of Device: Trade Name/Proprietary Name:	Bard® Endoscopic Suturing System
Common Usual Name:	Endoscopic Suture Device
Classification Name:	78KOG – Endoscopic Suture Device

B. Predicate Devices:

Company	*Trade Name*	*510(k)#*
1. U. S. Surgical Corp.	Auto Suture™ ENDO STITCH™ Suturing Device	#K934738
2. Ethicon Endo-Surgery, Inc.	ENDOPATH® Endoscopic Suturing System	#K980022

C. Description

The Bard® Endoscopic Suturing System consists of a capsule assembly with suction tubing and a fixed head knotpusher that attaches to the distal end of a

flexible endoscope or a through-the-scope knot pusher, plus a needle assembly, pusher wire, guidewire and suture cutter that all pass through an endoscope's biopsy channel. Also, included is a suture loader to facilitate loading suture tags into the needle, a syringe for flushing the suction tubing, and an detachable knot pusher handle. Only Bard® Suture Tags and the Bard® Endoscopic Handle may be used with the Bard® Endosocpic Suturing System.

D. Intended Use:

The Bard® Endoscopic Suturing System is used for endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for the approximation of tissue for the treatment of symptomatic Gastroesophageal Reflux Disease.

E. Technological Characteristics Summary:

The technological characteristics of the Bard® Endoscopic Suturing System is the same or similar to the predicate devices, in that the materials used to manufacture these products are the same type of medical grade stainless steels and plastics. The products all share common features such as a sterile, stainless steel needle housed in a capsule or suture loading unit at the distal end of the device. They all suture soft tissue by manually actuating the needle with a handle mechanism. They all are designed to allow reloading of sutures to deliver multiple stitches under endoscopic visualization. Further, the Bard® Endoscopic Suturing System and the predicated devices have the same or similar intended use, that is to place stitches and tie suture material to approximate soft tissue under endoscopic visualization.

F. Performance Data:

Biocompatibility, in vitro bench testing, animal and clinical testing has been completed and supports the safety and effectiveness of the Bard® Endoscopic Suturing System for its intended use.

The biocompatibility test results show that the materials used in the design and manufacture of the device are non-toxic and non-reactive to biologic tissues consistent with their intended use.

Bench test results show that the materials chosen and the design utilized in manufacturing the Bard® Endoscopic Suturing System, meet the established specifications necessary for consistent performance during their intended use.

The animal studies support the safety and effectiveness of the Bard® Endoscopic Suturing System. The studies document there were no complications/adverse reactions reported, and that the system is capable of safely and consistently placing sutures in the soft tissues within the stomach and esophagus.

Finally, the summary of human clinical experience under a 64 patient prospective randomized investigation and the non-U. S. patient experience supports the safety and effectiveness of the Bard® Endoscopic Suturing System for its intended use.