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.
% Mr. Peter N. Ruys
N. V. Kema
Utrechtseweg 310
NL-6812 AR Arnhem
The Netherlands

JUL 27 2015

Re: K003956
Trade/Device Name: Bard® EndoCinch™ 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): November 27, 2000
Received (Date on orig SE ltr): December 21, 2000

Dear Mr. Ruys,

This letter corrects our substantially equivalent letter of January 5, 2001.

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

510(k) Number (if known): K003956

Device Name: Bard® EndoCinch™ 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)

Miriam C. Provost for C. Witten
(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003956

K003956 (1 OF 3)

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

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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 C.R. Bard, Inc.
Address:	129 Concord Road, Bldg. #3 Billerica, MA 01821
Phone:	(978) 262-4866
Fax:	(978) 262-4878
Contact Person:	Beth A. Zis, R.A.C.
Date of Preparation:	November 17, 2000

B. Device Name

Trade Name:	Bard® EndoCinch™ Suturing System
Common/Usual Name:	Suturing Device
Classification Name:	Endoscopes and accessories

C. Predicate Device Name(s)
Trade Name:

Bard® Endoscopic Suturing System
Bard Interventional Products, Division of C. R. Bard, Inc.

Y-Knot Suture Clip
Innovasive Devices, Inc.

SutureLok
Smith & Nephew, Inc., Endoscopy Division

D. Device Description:
The Bard® EndoCinch™ Suturing System is a multi-component system consisting of a reusable handle, disposable capsule assembly, needle assembly, guidewire, pusher wire, clip delivery device, suture clip loader, suture clips, suture loader, suture loop tools and suture tag assemblies. Only the Bard® Endoscopic Handle and Bard® Suture Tags may be used with the Bard® EndoCinch™ Suturing System.

E. Intended 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.

F. Technological Characteristics Summary:
The Bard EndoCinch Suturing System is substantially equivalent to the Bard Endoscopic Suturing System. The system will now contain a clip delivery device and suture clips to secure the suture. The ring and plug of the suture clip are mated together to secure the two ends of the suture through manual actuation of the handle. This fixation, like the predicate devices, replaces

the knot component of the suture tag assembly. The clip delivery device also will cut the suture once the suture clip is secured by manually actuating the handle. The suture clips and delivery device will replace the current suture cutter and knot pushing devices contained in the kit. The remaining components of the current suture kit and the reusable handle are not changing.

G. Performance Data

Comparative performance testing was done, where appropriate, between the proposed EndoCinch™ suture clips and the current polypropylene knot. The clip delivery device was tested to assure that the suture clips can be delivered to cinch and cut the suture and the critical joints of the clip delivery device underwent tensile testing.

Comparative testing of the suture clips to the current knot demonstrated that the suture remains secure when exposed to the simulated conditions of food swallowing, lower esophageal sphincter forces and the gastric environment without degradation or loss of integrity.

Testing also demonstrated that the suture clip can be delivered to the intended location, and can secure and cut the suture in three versus nine intubations of the endoscope as compared to the current knot tying method used.