K973500 pg 1 of 3

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

BARD

OCT 16 1997

VI **510(k) Summary for the Bard® Endoscopic Overtube**

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (I)(3)(A) of the Act, an adequate summary of any information respecting safety and effectiveness follows.

A. Submitter Information:

- Name and address of submitter:
  Bard Interventional Products Division, C.R. Bard. Inc.
  129 Concord Road, Building 3
  Billerica, MA 01821

- Telephone (978) 663-8989
  Fax (978) 262-4878

- Contact Person:
  Marion Gordon, R.A.C.
  Senior Regulatory Affairs Coordinator

- Date of Preparation:
  October 8, 1997

B. Device Name:

- Trade Name: Bard® Endoscopic Overtube
- Common/Usual Name: Overtube
- Classification Name: Endoscope and accessories (per 21 CFR 876.1500)

C. Predicate Device Name:

- Trade Name: Bard® Endoscopic Overtube
- Trade Name: Olympus Splinting Tube ST-C3

D. Device Description:

- The Bard® Endoscopic Overtube consists of a flange bonded to a plastic sheath and is inserted into the esophagus through an initially placed bite block.

E. Intended Use of Device:

- The Bard® Endoscopic Overtube is intended to be used with an endoscope when repeated endoscopic intubation is anticipated, e.g., esophageal ligation, change of endoscopes, removal of multiple polyps and/or foreign bodies.

F. Technological Characteristics Summary:

- Both of the proposed and existing Bard® overtubes share a similar design consisting of a proximal cryolite flange, UV bonded to a polyvinyl chloride sheath with a distal tapered tip and is intended for use with an initially placed bite block. Both overtubes are indicated for twenty-five (25) reuses.

  The proposed overtube also employs an encapsulated stainless steel tempered wire coiled along the length of its sheath and externally encapsulated within the polyvinyl chloride as does the Olympus Splinting Tube.

Similarities and Differences Summary:

- Similarities

  Both the proposed and existing Bard® overtubes share a similar design consisting of a proximal flange UV bonded to a sheath with a distal tapered tip and is intended for use with an initially placed bite block. Either device is designed to protect the hypopharynx from the trauma of repeated intubations, the airway from aspiration and the esophagus during extraction of sharp objects or foreign bodies. The labeled warnings and contraindications remain the same and both overtubes are indicated for twenty-five (25) reuses.

  The proposed Bard® Endoscopic Overtube is similar in technological

characteristic as the Olympus, Splinting Tube ST-C3, with a wire coil along the length of its sheath that is encapsulated. Additionally, an overtube has a similar intended use as a splinting tube in aiding endoscope insertion through the tube to reach a target area and perform a specific function, while the surrounding anatomy is protected from potential trauma of endoscope reinsertion.

Differences

- The proposed Bard® Endoscopic Overtube will be somewhat longer and the distal tip will have a beveled rather than blunt taper. The sheath will include a frosted polyvinyl chloride for a lower friction surface and will have an encapsulated coil to maximize shaft ID for repeated intubations.

G. Performance Data:

- The Bard® Endoscopic Overtube has been subjected to nonclinical, tensile performance testing and biocompatibility testing. These tests conclude that this device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 1997

Marion Gordon, R.A.C.
Senior Regulatory Affairs Coordinator
Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road
Billerica, Massachusetts 01821-7031

Re : K973500
Bard® Endoscopic Overtube
Dated: September 15, 1997
Received: September 16, 1997
Regulatory class: II
21 CFR §876.5130/Product code: 78 KOG

Dear Ms. Gordon:

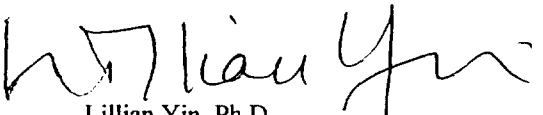
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K973500

Device Name: Bard® Endoscopic Overtube

Indications For Use:

To be used with an endoscope when repeated endoscopic intubation is anticipated, e.g., esophageal ligation, change of endoscopes, removal of multiple polyps and/or foreign bodies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P Sutling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973500

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

(Optional Format 1-2-96)