July 10, 2026

C.R. Bard, Inc.
Caitlin Bowles
Senior Regulatory Affairs Specialist
8195 Industrial Blvd.
Covington, Georgia 30014

Re: K253514
Trade/Device Name: Minnesota Four-Lumen Esophagogastric Tamponade Tube - 18 French (0092220); Blakemore Esophageal-Nasogastric Tube - 20 French (0092100); Blakemore Esophageal-Nasogastric Tube - 16 French (0092300)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: November 4, 2025
Received: November 6, 2025

Dear Caitlin Bowles:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SIVAKAMI VENKATACHALAM -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253514

Please provide the device trade name(s).

Minnesota Four-Lumen Esophagogastric Tamponade Tube - 18 French (0092220);
Blakemore Esophageal-Nasogastric Tube - 20 French (0092100);
Blakemore Esophageal-Nasogastric Tube - 16 French (0092300)

Please provide your Indications for Use below.

The Minnesota Four-Lumen Esophagogastric Tamponade Tube is indicated for the control of bleeding from esophageal varices.

The Blakemore Esophageal-Nasogastric Tubes are indicated for the control of bleeding from esophageal varices.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary - K253514

In accordance with 21 CFR §807.92, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter	C. R. Bard, Inc. 8195 Industrial Blvd Covington, GA 30014 Establishment Registration # - 1018233
Contact Person	Caitlin Bowles Senior Regulatory Affairs Specialist Telephone Number: 470-205-9024
Date Prepared	June 09, 2026
Subject Devices	Trade Name: Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes Common / Usual Name: Esophagogastric Balloon Tamponade Tube Classification Name: Gastrointestinal tube and accessories, 21 CFR §876.5980 Product Code: KNT Regulatory Classification: II
Predicate Device	Legally marketed device to which substantial equivalence is claimed for the Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes: • Primary Predicate: Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes – PreAmendment-KNT (C. R. Bard, Inc. f.k.a. Davol, Inc.); Legally marketed prior to May 28, 1976.

Device Description

The Minnesota Four-Lumen Esophagogastric Tamponade Tube and the Blakemore Esophageal-Nasogastric Tubes (Esophagogastric Balloon Tamponade Tubes) are indicated for the control of bleeding from esophageal varices.

All of the subject devices are made of flexible tubing and include two balloons - a gastric / stomach balloon and an esophageal balloon, which are inflated with air via inflation lumens during clinical use. The tubes use pressure from balloons to compress an area to help control bleeding. The devices also include one or more aspiration lumens, which are used to irrigate or suction gastric or esophageal contents.

Design variants include French size, length, number of lumens, number / location of suction holes (eyes), and size of the two balloons. Plastic plugs are included with the devices in the balloon inflation lumens. The plastic plugs maintain slight inflation of the balloons during shipment and storage to ensure product integrity. All devices include x-ray opaque red natural rubber latex. The subject devices are intended for prescription use only and should be used only by qualified healthcare professionals. All devices are provided non-sterile and are for single use only.

Minnesota Four-Lumen Esophagogastric Tamponade Tube: The Minnesota Four-Lumen Esophagogastric Tamponade Tube is a four-lumen, double-balloon tube designed for emergency control of bleeding esophageal varices and as a diagnostic aid in determining the source and/or extent of hemorrhage into the stomach. Third and fourth lumens facilitate suctioning above the esophageal balloon and in the stomach. The third lumen allows for suctioning of gastric contents via three alternating suction holes (eyes) at the distal tip below the stomach balloon. The Minnesota Tube device is differentiated based on the presence of the fourth lumen for esophageal aspiration. This lumen allows for irrigation and suctioning via two suction holes (eyes) located above the esophageal balloon. It includes four (4) plastic plugs.

Blakemore Esophageal-Nasogastric Tubes: The Blakemore Esophageal-Nasogastric Tubes are three lumen, double-balloon tubes designed for emergency control of bleeding esophageal varices and as a diagnostic aid in determining the source and/or extent of hemorrhage into the stomach. The third lumen allows for irrigation and suctioning of gastric contents via three alternating suction holes (eyes) at the distal tip below the gastric balloon. Includes two (2) plastic plugs. The Blakemore Esophageal-Nasogastric Tubes are available in two different sized variants. The larger size has a larger French size and longer esophageal balloon. The smaller size has a smaller French size and shorter esophageal balloon.

Indications for Use

The Minnesota Four-Lumen Esophagogastric Tamponade Tube is indicated for the control of bleeding from esophageal varices.

The Blakemore Esophageal-Nasogastric Tubes are indicated for the control of bleeding from esophageal varices.

Comparison of Technological Characteristics

Comparisons of the Minnesota Four-Lumen Esophagogastric Tamponade Tube (subject), Blakemore Esophageal-Nasogastric Tubes (subject), and the predicate device are provided in Table 1.

The design features and technological characteristics of the subject device are largely the same as the predicate device. The instructions for use have been modified to include additional plastic plug removal instructions. While differences exist related to procedural instructions in the subject device labeling and there are minor differences in device materials and dimensions, these differences do not raise different questions of safety and effectiveness.

Table 1. Comparison of the Subject (Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes) and Predicate (Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes) Devices

Design / Technological Characteristic	Subject Device: Minnesota Four-Lumen Esophagogastric Tamponade Tube Blakemore Esophageal-Nasogastric Tubes	Predicate Device (PreAmendment-KNT): Minnesota Four-Lumen Esophagogastric Tamponade Tube Blakemore Esophageal-Nasogastric Tubes
FDA Clearance Number	Subject of this submission	Not Applicable – PreAmendment device legally marketed before May 28, 1976
Labeling Characteristics		
Indications for Use	For the control of bleeding from esophageal varices.	For the control of bleeding from esophageal varices.
General Characteristics		
Sterility	Non-sterile	Non-sterile with instructions for the user to sterilize if desired
Single Use Only	Yes	Yes
Radiopaque	Yes	Yes
Materials		
Shaft, Balloon, and Funnel Materials	Natural Rubber Latex (X-Ray Opaque) Natural Rubber Latex Silicone Solution Shaft / Funnel Ink Rubber Cement Plastic Plugs	Natural Rubber Latex (X-Ray Opaque) Natural Rubber Latex Silicone Solution Shaft / Funnel Ink Rubber Cement Plastic Plugs
Dimensions / Specifications		
Number of Lumens	Minnesota Tube: 4 - Esophageal aspiration lumen, Gastric aspiration lumen, Stomach balloon lumen with stomach balloon arm, Esophageal balloon lumen with esophageal balloon arm Blakemore Tubes: 3 - Gastric aspiration lumen, Gastric balloon lumen, Esophageal balloon lumen	Minnesota Tube: 4 - Esophageal aspiration lumen, Gastric aspiration lumen, Stomach balloon lumen with stomach balloon arm, Esophageal balloon lumen with esophageal balloon arm Blakemore Tubes: 3 - Gastric aspiration lumen, Gastric balloon lumen, Esophageal balloon lumen
Number of Balloons	2	2
Stomach / Gastric Balloon Feature	Yes	Yes
Stomach / Gastric Balloon Length	Minnesota Tube Stomach Balloon: 3 ¾ inches Blakemore Tube Gastric Balloon: 1 ½ inches	Minnesota Tube Stomach Balloon: 3 ¾ inches Blakemore Tube Gastric Balloon: 1 ½ inches

Design / Technological Characteristic	Subject Device: Minnesota Four-Lumen Esophagogastric Tamponade Tube Blakemore Esophageal-Nasogastric Tubes	Predicate Device (PreAmendment-KNT): Minnesota Four-Lumen Esophagogastric Tamponade Tube Blakemore Esophageal-Nasogastric Tubes
Esophageal Balloon Feature	Yes	Yes
Esophageal Balloon Length	Minnesota Tube: 8 inches Blakemore Tube 20 Fr. Model: 8 inches Blakemore Tube 16 Fr. Model: 6 inches	Minnesota Tube: 8 inches Blakemore Tube 20 Fr. Model: 8 inches Blakemore Tube 16 Fr. Model: 6 inches
Overall Tube Length	Minnesota Tube: 41 inches Blakemore Tubes: 39 inches	Minnesota Tube: 39 inches Blakemore Tubes: 39 inches
French Size	Minnesota Tube: 18 French Blakemore Tubes: 16 French and 20 French	Minnesota Tube: 18 French Blakemore Tubes: 16 French and 20 French

Performance Data Summary

1. Biocompatibility Testing

Biocompatibility testing on the subject devices was carried out in alignment with the requirements for an External Communicating – Tissue / Bone / Dentin contacting device with prolonged contact duration per ISO 10993-1:2018 and FDA Guidance *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"*. The subject device was determined to be biocompatible for its intended use and was evaluated to the following standards:

- ISO 10993-3 – Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5 – Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6 – Biological evaluation of medical devices - Part 6: Tests for local effects after Implantation
- ISO 10993-10 – Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11 – Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23 – Biological evaluation of medical devices - Part 23: Tests for irritation

2. Performance Testing

Certain endpoints (as applicable) of the following standards have been deemed relevant to Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tube performance:

- ISO 20695:2020 - Enteral feeding systems - Design and testing

- ISO 10555-4:2023 - Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilation catheters

- ASTM F2503:2023 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

- ASTM F640:2020 - Standard Test Methods for Determining Radiopacity for Medical Use

To demonstrate intended device performance, as well as to support the substantial equivalence of the subject Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes to the predicate device, the technological and performance characteristics were evaluated by completion of the below testing endpoints:

- Balloon lumen functionality following plastic plug removal with tool (smooth hemostat)

- Esophageal balloon pressure (adapted from ISO 10555-4 section 4.4.1 and Annex A)

- Gastric balloon concentricity when inflated to manufacturer specified volume (adapted from ISO 20695 section 7.7.4 and Annex I)

- Gastric balloon integrity against burst when inflated to manufacturer specified volume after immersion in simulated gastric fluid (adapted from ISO 20695 section 7.7.5 and Annex J)

- Tensile test for the following joints when subjected to the specified minimum linear tensile force: Stomach and esophageal balloon arms (Minnesota Tube only), Distal tip of tube shaft, Esophageal balloon area of tube shaft, and Joint between tube shaft and inflation lumens (adapted from ISO 20695 sections 5.5, 7.3, and Annex C)

- Gastric balloon volume (adapted from ISO 20695 section 7.7.1 and Annex G)

- Materials of construction evaluation and MR environment hazard analysis determining the subject device may be labeled MR Safe (ASTM F2503)

- Radiopacity of red x-ray opaque natural rubber latex (ASTM F640)

- Plastic plug removal tensile force - minimum and maximum force to remove plastic plugs

To demonstrate the device meets user needs and to validate changes to the subject device instructions for use, design validation testing for the following procedural steps was completed in a simulated use scenario by representative intended users (clinicians):

- Plastic plug removal - Users were able to remove the plugs from the device following the instructions for use.

- Set Up - Users were able to set up the device following the instructions for use.

- Traction - Users were able to apply traction to the device following the instructions for use.

The subject Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tube devices met the requirements of the above standards and performance endpoints.

Conclusion

The subject Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes are substantially equivalent to the legally marketed predicate device as demonstrated by the same intended use, same indications for use, and similar / equivalent design features as the predicate device, Minnesota Four-Lumen Esophagogastric Tamponade Tube and Blakemore Esophageal-Nasogastric Tubes (PreAmendment-KNT).

The subject device is substantially equivalent to the legally marketed predicate device, and nonclinical test data demonstrate that the subject device is safe and effective and that any differences in technological characteristics do not raise different questions of safety and effectiveness.