March 7, 2018

Globus Medical, Inc.
Lori Burns
Director, Regulatory Affairs
2560 General Armistead Ave.
Valley Forge Business Center
Audubon, Pennsylvania 19403

Re: K171939
Trade/Device Name: ALVUE Balloon Dilation System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 22, 2018
Received: January 23, 2018

Dear Lori Burns:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171939

Device Name
ALVUE™ Balloon Dilation System

Indications for Use *(Describe)*
The ALVUE™ Balloon Dilation System is indicated for patients undergoing surgical procedures requiring tissue retraction including the following procedures: endoscopic; laparoscopic; general surgery; plastic and reconstructive surgery; spine surgery; orthopedic surgery; thoracoscopic surgery; and procedures in the extraperitoneal space. The system is intended to create an operative space by dissecting layers of connective tissue along natural tissue planes of separation of the extraperitoneal, subcutaneous extremity, or thoracic space.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: ALVUE™ Balloon Dilation

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Lori Burns
Director, Regulatory Affairs

Alternate Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: January 22, 2018

Device Name: ALVUE™ Balloon Dilation System

Common Name: Surgical Balloon Dilator

Classification: Per 21 CFR as follows:
§876.1500 Endoscope and accessories
Product Code(s): GCJ
Regulatory Class: II, Panel Code: 87

Primary Predicate: Pajunk Disposable Balloons and Balloon Systems (K090631)

Predicates: Spacemaker Surgical Balloon Dissector (K973046)

Reference Devices:
AFFIRM™ VCF System (K110998)
CRE Balloon Dilatation Catheter (K110833)
Gyrus ACMI Nephro EZDilate Nephrostomy Balloon Dilation Catheter (K132383)
Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheters (K143609)

Purpose:
The purpose of this submission is to request clearance for the ALVUE™ Balloon Dilation System.

Device Description:
The ALVUE™ Balloon Dilation System is a surgical instrument that consists of an inflatable nylon balloon attached to the distal end of a dilator. ALVUE™ is used to dilate soft tissue to gain access to the surgical site and is available in a variety of sizes to accommodate the anatomical needs of the patient. The system includes accessories for inflation. ALVUE™ is a sterile single use device.

Indications for Use:
The ALVUE™ Balloon Dilation System is indicated for patients undergoing surgical procedures requiring tissue retraction including the following procedures: endoscopic; laparoscopic; general surgery; plastic and reconstructive surgery; spine surgery; orthopedic surgery; thoracoscopic surgery; and procedures in the extraperitoneal space. The system is intended to create an operative space by dissecting layers of connective tissue along natural tissue planes of separation of the extraperitoneal, subcutaneous extremity, or thoracic space.

Performance Data:
Mechanical testing (inflation volume and pressure, axial tension, and fatigue) was conducted in accordance with ISO 10555-1:2013, *Sterile, Single-Use Intravascular Catheters – Part 1: General Requirements* and ISO 10555-4:2013, *Sterile, Single-Use Intravascular Catheters – Part 4: Balloon Dilation Catheters*. Performance data demonstrates substantial equivalence to the predicate. Biocompatibility testing was performed in accordance to ISO 10993-1 on patient contacting materials.

Technological Characteristics:
The ALVUE™ Balloon Dilation System has similar technological characteristics as the predicate devices including design, intended use, material composition, and function. The subject and predicate devices consist of cylindrical balloons which function to dilate soft tissue. The subject device uses fluid to inflate the balloon while the predicates use either fluid or gas. These systems are used to create an operative space by dissecting layers of connective tissue along natural planes of separation of extraperitoneal, subcutaneous extremity, or thoracic space. ALVUE™, unlike the predicates, is not indicated for vascular surgery nor laparoscopic surgery requiring a sealed port of access.

Basis of Substantial Equivalence:
ALVUE™ Balloon Dilation System have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject instruments to the predicate devices.