DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 23, 2017

Globus Medical, Inc.
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K162618
Trade/Device Name: CONCORD Plus™ Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: December 8, 2016
Received: December 9, 2016

Dear Dr. Baker:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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)*
K162618

Device Name
CONCORD Plus™ Radiopaque Bone Cement

Indications for Use *(Describe)*
CONCORD Plus™ Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

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 CONCORD Plus Radiopaque Bone Cement

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800
Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: December 8, 2016

Device Name: CONCORD Plus™ Radiopaque Bone Cement
Classification: Per 21 CFR §888.3027 Polymethylmethacrylate (PMMA) bone cement.
Product Code: NDN
Regulatory Class: II, Panel Code: Orthopedic 87

Predicate(s):
Primary CONCORD™ Radiopaque Bone Cement (K042168)
Additional VertaPlex® HV Radiopaque Bone Cement (K091606)

Purpose:
The purpose of this submission is to request clearance of the CONCORD Plus™ Radiopaque Bone Cement.

DEVICE DESCRIPTION:
The CONCORD Plus™ Radiopaque Bone Cement is a high-viscosity, radiopaque, self-curing, PMMA bone cement. It is provided sterile, as a two component system, a liquid component and a powder component which are mixed together prior to use to form the cement. The bone cement is intended for single use only.

INDICATION FOR USE:
CONCORD Plus™ Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Performance Data:
Performance data was conducted in accordance with the *Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement*, July 17, 2002. Performance data demonstrates substantial equivalence to the predicate.

Performance testing, chemical testing and handling properties were conducted to characterize CONCORD Plus™ Radiopaque Bone Cement compared to the

predicate in compliance with ASTM D732-10, ASTM D5045-14, ASTM F2118-14, ASTM D638-10, ASTM F451-08, ASTM D2990-09, and ISO 5833:2002.

CONCORD Plus™ Radiopaque Bone Cement is provided sterile. The powder component is sterilized with gamma radiation to a Sterility Assurance Level (SAL) of 10^{-6}. The liquid component is sterilized with filtration methods to a SAL of 10^{-3}. The outer packaging containing the liquid and powder components is sterilized by ethylene oxide gas to a SAL of 10^{-6}.

Technological Characteristics:
The subject CONCORD Plus™ Radiopaque Bone Cement has the same fundamental scientific technology as the predicate CONCORD™ Radiopaque Bone Cement. The subject device has the same chemical composition, sterilization methods and meets the same pyrogen limit specification of ≤20 EU/device as the predicate. The subject CONCORD Plus™ is a high viscosity bone cement similar to the predicate VertaPlex HV Bone Cement.

Basis of Substantial Equivalence:
CONCORD Plus™ Radiopaque Bone Cement has been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject bone cement to the predicate devices.