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

February 6, 2017

Dragon Crown Medical Co., Ltd.
Mr. Zhi Yong Song
Supervisor of Product Regulation
6F, Kehui Building, No. 109, Shunhua Road, High-Tech Development Zone
Jinan, Shandong Province 250101
China

Re: K162283
Trade/Device Name: DCM Kyphoplasty System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: January 3, 2017
Received: January 9, 2017

Dear Mr. Song:

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)*
K162283

Device Name
The DCM Kyphoplasty System

Indications for Use *(Describe)*
The DCM Kyphoplasty System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate(PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

山东冠龙医疗用品有限公司

Section 5 of Traditional 510(K) Submission:

510 (K) Summary

This 510(K) Summary of safety and effectiveness information is being submitted in accordance with requirement of 21 CFR807.92

1. Date of Submission: Feb. 2, 2017
2. Submitter / 510(K) Holder

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3. Proposed Device Name

Trade name: DCM Kyphoplasty System
Common name:Kyphoplasty System
Classification Name: Polymethylmethacrylate (PMMA) Bone Cement
Cement, bone, vertebroplasty
Device Class: Class II
Classification Panel: Orthopedic Panel
Product Code: NDN, HRX
Regulation Number: 21 CFR 888.3027, 21 CFR 888.1100

4. Predicate Devices

Predicate Devices:
510 (k) Number: K143006
Product Name: GUARDIAN-SG Inflatable Bone Expander System
Submitter: BM KOREA CO., LTD.

5. Indication for Use

DCM Kyphoplasty System is intended to be used for the reduction and fixation of fractures and/or creation

of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

6. Device Description

The DCMKyphoplasty System is designed to reduce compression fracture and create a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

DCM Kyphoplasty System contains balloon catheter, balloon inflator, puncture needle and tool kit.

The balloon catheter is used to position inside of the vertebral body where it is inflated to make a cavity. The balloon inflator is used to inflate the balloon catheter that is filled with a contrast agent. The puncture needle is used to percutaneous puncture during the surgery and have two types: locking and rotating. The tool kit is used to support to perform the surgery and fill the bone cement. All parts of DCM Kyphoplasty System are supplied sterile and are single use only.

The balloon catheter has four specifications: Φ9×15, Φ12×19, Φ14×17 and Φ17×22. Balloon Inflator has two specifications: 20ml/30atm, 25ml/30atm. Puncture Needle has seven specifications: Φ2.5×100, Φ2.5×130, Φ3.0×100, Φ3.2×100, Φ3.2×130, Φ3.5×126, Φ4.0×126.

The tool kit is consisting of bone expander, spiral propeller, guide needle, expansion tube, working cannula, solid vertebral drill, hollow vertebral drill, push rod, bone cement injector and locator. They are supplied sterile and are single use only.

7. Sterilization

DCM Kyphoplasty System is provided sterile and is for single use only. The ETOgas sterilization process isvalidated with a resulting sterility assurance level (SAL) of 10^{-6}.It meets requirements of ISO 11135, sterilization of health-care products for ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices.

ETOresidual testing was also performed and the test result meets specification.

8. Packaging

The package of partsof DCM Kyphoplasty System has four levels. Firstlyeach parts is placed in the sterilization package and heat sealed. Secondly each sterilization package is placed in inner box. Thirdly four inner boxes are packaged in middle box. Finally, this middlebox isplaced in a shipping box.

Expiration dating testing was conducted using methodof the industry standard AAMI/ANSI/ISO 11607Packaging for Terminally Sterilized Medical Devicesfor accelerated aging and real-time aging was also performed.

9. Materials

All materials used in the manufacture of the DCM Kyphoplasty System can meet the requirements of AAMI/ANSI/ISO 10993, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process.

Typical material hasPolyurethane, Platinum, Polycarbonate(PC), Stainless Steel S30408, S51740, ABS etc.

10. Non-Clinical Testing

Product testing of DCM Kyphoplasty System was performed on final sterilized devices. Testing was completed, including:dimensional, inflation/deflation, balloon size, insertion/withdraw force, fatigue testing and tensile strength. All testing met theacceptance criteria.

Biocompatibility testing was performed per AAMI/ANSI/ISO 10993 as required for a temporary bone/tissuecontacting device. All materials were found to be biocompatible and suitable for this use.

11. Comparison Table of the Technological Characteristics

No	Compare Items	Proposed Device： DCM Kyphoplasty System	Predicate Device 510(K) No.K143006	Comparison Result
1	Class	Class II	Class II	Same
2	Product Code	HRX, NDN	HRX, NDN	Same
3	Intended Use	DCM Kyphoplasty System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	GUARDIAN-SG Inflatable Bone Expander System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	Same
4	Design	DCM Kyphoplasty System consists of four components: * Balloon Catheter * Balloon Inflator * Puncture Needle * Tool Kit The balloon catheter has four specifications: Φ9×15, Φ12×19,	The GUARDIAN-SG IBES components are Inflatable Bone Tamp (balloon catheter, compressor) and accessory kit. and balloon catheter' main components are the shaft, Yhub and the inflatable balloon located at the distal tip	Similar

		Φ14×17 and Φ17×22 Balloon Inflator: 20ml/30atm 25ml/30atm Puncture Needle: Φ2.5×100, Φ2.5×130, Φ3.0×100, Φ3.2×100, Φ3.2×130, Φ3.5×126, Φ4.0×126	The balloon catheter has three specifications: BMK10, BMK15, BMK20	
5	Material	Balloon Catheter is made of Polyurethane, Platinum, Polycarbonate(PC), Stainless Steel S30408 Balloon Inflator is made of Polycarbonate(PC), Nylon reinforced polyurethane, Brass, Stainless Steel S30408, Nylon(PA6), ethylene propylene diene monomer Puncture Needle is made of Stainless Steel S30408, S51740, ABS, Polycarbonate(PC) Other parts are made of Plastic and Stainless Steel etc.	All materials used in the GUARDIAN-SG Inflatable Bone Expander System are Plastic and Stainless Steel etc.	Similar
6	Biocompatibility	All materials are made of stainless steel & plastic material etc. and used in the DCM Kyphoplasty System can meet the requirements of AAMI/ANSI/ISO 10993, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process.	All materials used in the GUARDIAN-SG Inflatable Bone Expander System can meet the requirements of FDA requirement related to biocompatibility.	
7	Properties	Product testing of DCM Kyphoplasty System was performed on final sterilized devices. Testing was completed, including: dimensional, inflation/deflation, balloon size, insertion/withdraw force, fatigue testing and tensile strength. All testing met the acceptance criteria. Biocompatibility testing was performed per AAMI/ANSI/ISO 10993	The testing of the GUARDIAN-SG Inflatable Bone Expander System included functional, such as balloon compliance, deflation time, insertion / withdraw force and fatigue testing as well as mechanical testing, such as tensile strength.	Similar
8	Sterilization	DCM Kyphoplasty System is provided	The Balloon catheter, compressor and	Similar

		sterile and is for single use only. The ETO gas sterilization process is validated with a resulting sterility assurance level (SAL) of 10^{-6}. It meets requirements of ISO 11135, ETO residual testing was also performed and the test result meets specification.	the accessory kit are supplied sterile and disposable use.	
9	Standards met	AAMI / ANSI / ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility) ISO 11135 Second edition 2014, sterilization of health-care products ¿ ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)	AAMI / ANSI / ISO 10993-1, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility) ISO 11135, sterilization of health-care products, ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)	Same
10	Single use	Yes	Yes	Same
11	Package	The package of parts of DCM Kyphoplasty System has four levels. Firstly each parts is placed in the sterilization package and heat sealed. The top plastic is APET and bottom paper is Tyvek1073B. Secondly each sterilization package is placed in inner box. Thirdly four inner boxes are packaged in middle box. Finally, this middle box is placed in a shipping box.	The components are placed in a thermoformed PETG/PET tray. The heat sealed pouches are placed in white shelf cartons and then packaged in a corrugated shipper box.	Similar

12. Substantially Equivalent Conclusion

DCM Kyphoplasty System has same intended use than the predicate device and similar technological characteristics as the predicate device. The proposed device, DCM Kyphoplasty System, is determined to be Substantially Equivalent (SE) to the predicate device, K143006 GUARDIAN-SG Inflatable Bone Expander System, in respect of safety and effectiveness.