May 29, 2018

HANCHANG Co., Ltd.
% GeumHyeon Kim
Lead Consultant
DT&S Co., Ltd.
#1206, Mario Tower, 28, Digital-ro 30-gil
Guro-gu, Seoul 08389
Republic of Korea

Re: K172871
Trade/Device Name: SpineKure Kyphoplasty System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: March 7, 2018
Received: April 18, 2018

Dear GeumHyeon Kim:

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,

Katherine D. Kavlock -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172871

Device Name
SpineKure Kyphoplasty System

Indications for Use *(Describe)*
The SpineKure 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. This 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)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

March. 23. 2018

2. Submitter's Information [21 CFR 807.92(c)(1)]

- Name of Manufacturer: HANCHANG Co., Ltd
- Address: #301-204 Bucheon Techno-park, 345, Seokcheon-ro, Bucheon-si, Gyeonggi-do, 14501, Republic of Korea
- Telephone No.: +82-32-234-0033
- Fax No.: +82-32-234-0040

3. Submission Correspondent

- Name of company: DT&S Co., Ltd.
- Address: #1206, Mario Tower, 28, Digital-ro 30-gil, Guro-gu, Seoul, 08389, Republic of Korea
- Contact Name: GeumHyeon Kim
- Contact Title Lead Consultant
- E-mail Address gh.kim@dtns.co.kr
- Telephone No.: +82-2-357-8401
- Fax No.: +82-2-357-8027

4. Trade Name, Regulation Name, Classification [21 CFR 807.92(c)(2)]

Trade/Device Name	SpineKure Kyphoplasty System
Common Name	Inflatable Bone Tamp
Regulation Number	21 CFR 888. 3027
Regulation Name	Polymethylmethacrylate (PMMA) bone cement
Regulation Class	Class II
Product Code	NDN, HRX
Product Code Name	Cement, Bone, Vertebroplasty

5. Identification of Predicate Device(s) [21 CFR 807.92(c)(3)]

Predicate device #1

- 510(k) Number: K153296
- Manufacturer: IMEDICOM Co., Ltd.
- Device Name: MEDINAUT Kyphoplasty System

Predicate device #2

- 510(k) Number: K150322
- Manufacturer: Pan Medical Ltd.
- Device Name: InterV Kyphoplasty Catheter and InterV Kyphoplasty Catheter (Mini)

Predicate device #3

- 510(k) Number: K131824
- Manufacturer: CareFusion
- Device Name: AVAflex Vertebral Balloon System

6. Description of the Device [21 CFR 807.92(c)(4)]

The SpineKure Kyphoplasty System is designed to reduce spinal compression fracture and restore sagittal alignment by creating a space in the vertebral body to facilitate the insertion of bone cement. The SpineKure Kyphoplasty System is comprised of a Balloon Catheter, Balloon Inflator and Cement Delivery System (Accessories kit).

The Balloon Catheter's main components are the shaft, hub and the inflatable balloon located at the distal tip. The surface of balloon is covered with a silicone lubricant to enhance the insertion and withdrawal of catheter. Radiopaque markers located at the distal and proximal end of deflated working surface allow fluoroscopic visualization of the deflated balloon catheter during positioning.

The Balloon Inflator (SBI) is a disposable device with an integral pressure gauge.

The Cement Delivery System (SCDS) are consist of Bone Access Needle (SBN), Cement Filler & Pusher (SFP), Cannula & Expander (SCE), Drill Bit (SDB), Wire-pin (SWP-T, SWP-R).

7. Indications for use [21 CFR 807.92(c)(5)]

The SpineKure 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. This system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

#301-204 Bucheon Techno-park, 345, Seokcheon-ro,
Bucheon-si, Gyeonggi-do, 14501, Republic of Korea

8. Determination of Substantial Equivalence

The SpineKure Kyphoplasty System are substantially equivalent to legally marketed predicate devices with respect to indications for use and technology characteristics. The proposed device also has similar designs and configurations with the predicate devices as well as physical specifications including the size and shape, and material. Therefore, the SpineKure Kyphoplasty System is substantially equivalent to the predicate device and does not raise any new issues of safety or effectiveness. The below table presents the comparisons for predicate devices:

	Proposed Device	Predicate Device #1	Predicate Device #2	Predicate Device #3
Device Name	SpineKure Kyphoplasty System	MEDINAUT Kyphoplasty System	InterV Kyphoplasty Catheter and InterV Kyphoplasty Catheter (Mini)	VAflex Vertebral Balloon System
510(k) Number	K172871	K153296	K150322	K131824
Manufacturer	HANCHANG Co. Ltd.	IMEDICOM Co., Ltd.	Pan Medical Ltd.	CareFusion
Product Code	HRX, NDN	HRX, NDN	HRX, NDN	HRX, NDN
Device Class	II	II	II	II
Indications for Use	The SpineKure 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. This system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	The MEDINAUT Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes 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.	InterV Kyphoplasty Catheter are intended to be used for reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethymethacrylate (PMMA) bone cements).	Intended for reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with CareFusion Radiopaque Bone Cement).

#301-204 Bucheon Techno-park, 345, Seokcheon-ro,
Bucheon-si, Gyeonggi-do, 14501, Republic of Korea

	Proposed Device	Predicate Device #1	Predicate Device #2	Predicate Device #3
Components	1) Balloon Bone Catheter 2) Balloon Inflator 3) Cement Delivery System - Bone Access Needle, Cement Filler & Pusher, Cannula & Expander, Drill Bit, Wire-pin Trocar, Wire-pin Round	1) Bone Catheter 2) Expander Syringe 3) Kit - Needle Pipe, Needle Pin, Expander, Cannula, Spacer, Guide Wire, Wire Pin, Cement Pusher, Cement Filler, and Guide wire	1) Balloon Bone Catheter 2) Bone access tools - Bone access needle, Kirschner wire, Bone access drill, Curette, Bone access cannula 3) Cement delivery tools - Cement delivery cannula, Cement dispenser 4) Inflation device	1) Balloon Bone Catheter 2) Accessory Kit
Specifications				
Balloon Size	10mm, 15mm, 20mm	10mm, 15mm, 20mm	10mm, 15mm, 20mm	15mm, 20mm, 30mm
Balloon Material	Thermoplastic Polyurethane	Thermoplastic Polyurethane	Polyurethane	Polyurethane
Max. Inflation Pressure	400 Psi	350 Psi	750 Psi	400 Psi
Max. Recommended Inflation Volume	10 mm balloon: 3 ml 15 mm balloon: 5 ml 20 mm balloon: 7 ml	10 mm balloon: 3 ml 15 mm balloon: 5 ml 20 mm balloon: 7 ml	10 mm balloon: 4 ml 15 mm balloon: 4 ml 20 mm balloon: 6 ml	15 mm balloon: 4 ml 20 mm balloon: 6 ml 30 mm balloon: 8 ml
Balloon Shape	Cylindrical	Cylindrical	Cylindrical	Cylindrical
Radiopaque Marker	Yes	Yes	Yes	Yes
Packaging information	Pouch (Medical grade paper), PE Film, Blister Pack, Cardboard Box	Pouch, Tyvek Blister Tray, Cardboard Box	Not known	Not known
Sterilization	EtO Sterilization	Gamma Sterilization	EtO Sterilization	Not known
Biocompatibility	Meets ISO 10993	Meets ISO 10993	Not known	Not known

9. Non-Clinical Test Summary

1) Biocompatibility tests were performed in accordance with ISO 10993- 5, 10, 11 as well as the FDA's 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 devices have been evaluated through the following tests:

   - ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: tests for in vitro cytotoxicity
   - ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: tests for irritation and skin sensitization
   - ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity including the pyrogen test

2) Verification activities including mechanical and functional testing as required by the risk analysis were performed to evaluate the performance and the safety of the subject devices and the test results met the preset criteria and it does not raise any new issues of safety or effectiveness.

   - Balloon deflation time
   - Burst pressure (constrained, unconstrained)
   - Fatigue strength
   - Balloon dimension before and after inflation,
   - Insertion and withdrawal force
   - Tensile bond strength

3) The shelf life test of the device were conducted in accordance with ASTM F1980-07.

4) The sterilization validation confirmed that the sterilization cycle maintained a sterility assurance level (SAL) of 10^{-6} in accordance with the following standard:

   - ISO 11135-1:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

5) The packaging integrity testing were conducted with visual inspection, seal strength and dye penetration test per ISTA-2A, ASTM F1929 and ASTM F88

10. Clinical Test Summary

N/A- No clinical tests were conducted for this submission

11. Conclusion [21 CFR 807.92(b)(3)]

Based on those information, we conclude that the SpineKure Kyphoplasty System is substantially equivalent to the predicate devices