DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 29, 2016

IMEDICOM Company, Limited
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K153296
Trade/Device Name: MEDINAUT Kyphoplasty System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: July 1, 2016
Received: July 5, 2016

Dear Ms. Chung:

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 Parts 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" (21CFR 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,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153296

Device Name

MEDINAUT Kyphoplasty System

Indications for Use *(Describe)*

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.

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.

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510(k) Summary

(K153296)

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 1, 2016

1. Applicant / Submitter

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2. Submission Correspondent

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3. Device

- Trade Name: MEDINAUT Kyphoplasty System
- Common Name: Inflatable Bone Tamp
- Classification Name: Arthroscope
  Cement, Bone, Vertebroplasty
- Product Code: NDN, HRX
- Classification regulation: Class II, 21 CFR 888.3027 / 21 CFR 888.1100

4. Predicate Device:

- MEDINAUT Kyphoplasty System by IMEDICOM Co., Ltd. (K133669)
- KyphX Inflatable Bone Tamp by Kyphon Inc. (K010246, K041454, K981251)

5. Description:

The MEDINAUT Kyphoplasty System is designed to reduce compression fracture and create a void in cancellous bone in the spine, tibia, radius, and calcaneus. Bone cement insertion using cement dispensing plunger is applied for spinal use only.

The MEDINAUT Kyphoplasty System consists of the MEDINAUT-X (Inflatable Bone Expander System) and MEDINAUT-I (Cement Dispenser System).

The MEDINAUT-X is comprised of a Balloon Catheter and a Bone Expander Syringe. The Balloon Catheter's main components are the shaft, Y-hub and the inflatable balloon located at the distal tip. The inflatable balloon is covered with a maximum 0.03g of silicone fluid to enhance lubricity when the balloon catheter is inserted in the cannula. 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 Catheter and Bone Expander Syringe are supplied sterile and are disposable.

The MEDINAUT-I is a cement dispenser system consisting of a Needle Pipe, Needle Pin, Wire Pin, Cannula, Expander, Spacer, Cannula Expander, Cement Pusher, Cement Filler, and Guide Wire. They are supplied sterile and are disposable.

6. Indication for use:

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.

7. Basis for Substantial Equivalence

The MEDINAUT Kyphoplasty System is identical to the device made by our company cleared under K133669. There are no modifications occurred since 510k clearance including raw materials, design, and manufacturing processes. The purpose of this 510k is to add more anatomic sites(adding the claims of use in tibia, radius and calcaneus) to the indications for use statement and we are presenting a reference predicate device, Kyph X Inflatable Bone Tamp by Kyphon Inc. (K010246, K041454, and K981251),which have the same anatomic site use claims.

As stated above, the subject device itself is exactly identical to the primary predicate device (K133669). When comparing to the KyphX Inflatable Bone Tamp by Kyphon Inc. (K010246, K041454, and K981251), the subject device has the same indications for use and the technology used. The subject device also has similar designs and configurations as well as physical specifications to the KyphX Inflatable Bone Tamp. The devices are used in the same manner, perform the same functions, are of similar size and shape, and constructed from the similar material, and physical specifications.

	Subject Device	Primary Predicate Device	Reference Predicate Device
Device Name	MEDINAUT Kyphoplasty System	MEDINAUT Kyphoplasty System	KyphX Inflatable Bone Tamp
510k Number	K153296	K133669	K010246, K041454, K981251
Manufacturer	IMEDICOM Co., Ltd.	IMEDICOM Co., Ltd.	Kyphon Inc.
Product Code	HRX, NDN	HRX, NDN	HRX
Common Name	Inflatable Bone Tamp	Inflatable Bone Tamp	Inflatable Bone Tamp
Indication for use	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.	The MEDINAUT Kyphoplasty System is intended to be used for the reduction of fracture 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 procedures, such as kyphoplasty	KyphX® Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with KyphX® MHV-RTM Bone Cement), hand, tibia, radius and calcaneus.
Components	Same as Primary Predicate Device(K133669)	▪ Bone Catheter ▪ Expander Syringe ▪ Kit (Needle Pipe, Needle Pin, Expander, Cannula, Spacer, Guide Wire, Wire Pin, Cement Pusher, Cement Filler, and Guide wire)	▪ Bone Catheter ▪ Expander Syringe ▪ Kit (Bone Access Needle, Introducer System, Precision Drill, Cannula, Expander, Spacer, Cement Pusher, Cement Filler and Guide Wire)
Balloon Size	Same as Primary Predicate Device(K133669)	10mm, 15mm, 20mm	10mm, 15mm, 20mm
Bone Tamp Max. Inflation Pressure	Same as Primary Predicate Device(K133669)	350 PSI	400 PSI
Composition of Material Balloon tip Radiopaque Marker Expander body Accessory kit	Same as Primary Predicate Device(K133669)	Thermoplastic Polyurethane Platinum Polycarbonate & ABS Stainless Steel & ABS	Thermoplastic Polyurethane Platinum Polycarbonate & ABS Stainless Steel & ABS
Packaging	Same as Primary Predicate Device(K133669)	Pouch, Tyvek Blister Tray, Cardboard Box	Pouch, Tyvek Blister Tray, Cardboard Box
Sterilization	Same as Primary Predicate Device(K133669)	Gamma Sterilization	Gamma Sterilization

Biocompatibility	Same as Primary Predicate Device(K133669)	Meets ISO 10993	Meets ISO 10993

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137-1, 2, 3 and ISO 11737-1, 2, 3, and the test results met the pre-set criteria.
- The tests to validate the shelf life of the device were conducted and the test results validated 1 year shelf life.
- Biocompatibility tests were performed in accordance with ISO 10993-4, 5, 10, 11, and the test results supported that the subject devices are biocompatible.
- Various bench tests including balloon deflation time, burst pressure constrained, burst pressure unconstrained, fatigue strength, balloon dimension before and after inflation, insertion and withdrawal force and tensile bond strength were performed to evaluate the performance and the safety of the subject devices and the test results met the pre-set criteria.

The test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

Based on the similarities, we conclude that the MEDINAUT Kyphoplasty System is substantially equivalent to the predicate devices.