MEDINAUT Kyphoplasty System 510k Summary

APR 0 4 2014

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

1. **Date:** Mar 24, 2014

2. **Applicant / Sponsor**

	Company
Name	IMEDICOM Co., Ltd.
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Contact	Ki Ung. Choi

3. Submission Contact Person

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4. Proposed Device Identification:

Proprietary Name – MEDINAUT Kyphoplasty System
Common Name – Inflatable Bone Tamp
Classification Name – Arthroscope

Predicate Device:
KyphX Inflatable Bone Tamp, K010246 & K041454
Kyphon Inflatable Bone Tamp, K981251

5. Proposed Device Classifications & Citations:

Classification: Class II
Product Code A: NDN
Regulation Number: 21CFR§888.3027
Review Panel: Orthopedic

Classification: Class II

Product Code B: HRX

Regulation Number: 21CFR§880.1100

Review Panel: Orthopedic

6. Predicate Device Identification:

510(k) Number: Primary Predicate: K041454
Secondary Predicates: K010246 and K981251

Product Name: KyphX® Inflatable Bone Tamp

Manufacturer's Name: Kyphon Inc. (Medtronic)

7. Device Description:

The MEDINAUT Kyphoplasty System is designed to reduce spinal compression fracture and restore sagittal alignment. By creating a space in the vertebral body it facilitate the insertion of bone cement through the use of the cement dispensing plunger. The benefits of MEDINAUT Kyphoplasty System are the reduction in back pain and increase of patient's functional abilities, allowing a return to the previous level of activity.

It consists of Balloon Catheter, Bone Expander Syringe, Needle Pipe, Needle Pin, Wire Pin (Troca Type, Round Type), Cannula, Expander, Spacer, Cement Pusher, Cement Filler, and Guide Wire. It is supplied sterile and for single disposable use.

The MEDINAUT Kyphoplasty System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The system is substantially equivalent in design, function and intended use to the predicate devices.

8. Indication for use:

The MEDINAUT 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.

9. Bench Test Data:

The MEDINAUT Kyphoplasty System complies with the internal quality control procedure of IMEDICOM Co., Ltd. and the characteristics are compared with Kyphon Inflatable Bone Tamp.

Test	Test Criteria	Test Result	
		MEDINAUT Kyphoplasty system	Kyphon Inflatable Bone Tamp
Tensile Bond Strength	Outer shaft and Hub with the 1mm/sec Test report#; IMT-TBST12-01	IBE-15; 20.85kgf	K13A; 14.76kgf
Fatigue strength	No burst and leakage at 15 cycles of maximum pressure limit 400psi Test report#; IMT-FST12-01	IBE-10; Pass IBE-15; Pass IBE-20; Pass	K13A; Pass K09A; Pass K08A; Pass

Test	Test Criteria	Test Result	
		MEDINAUT Kyphoplasty system	Kyphon Inflatable Bone Tamp
Balloon deflation time	Compare the performance (seconds) Test report:IMT-BDT12-01	IBE-10 2ml; 0.50 sec. 3ml; 0.76 sec. IBE-15 3ml; 0.51 sec. 5ml; 1.16 sec. IBE-20 3ml; 0.47 sec. 5ml; 1.12 sec. 7ml; 1.29 sec.	K13A 2ml; 0.27 sec. 4ml; 0.62 sec. K09A 2ml; 0.28 sec. 4ml; 0.62ml K08A 2ml; 0.31 sec. 4ml; 0.54 sec. 6ml; 0.69 sec.
Burst pressure constrained	400 psi at the Constrained jig for 30 seconds Test report: IMT-BPC12-08	IBE-10; 3.5ml Pass IBE-15; 5.5ml Pass IBE-20; 7.5ml Pass	K09A; 5.5ml Pass K08A; 7.5ml Pass
Burst strength unconstraint	Measure the burst inflation pressure Test report#: IMT-BST12-01	IBE-10; 250psi IBE-15; 207psi IBE-20; 183psi	K09A; 243psi K08A; 237psi
Balloon dimension before and after the inflation	Initial balloon length IBE-10; 10mm IBE-15; 15mm IBE-20; 20mm Test report#; IMT-IDT11-02	Balloon Diameter after inflation IBE-10, 3ml inflation; 14.1mm IBE-15, 5ml inflation; 17.1mm IBE-20, 7ml inflation; 19.3mm Balloon Length after inflation IBE-10, 3ml inflation; 16.3mm IBE-15, 5ml inflation; 22.2mm IBE-20, 7ml inflation; 29.4mm	Balloon Diameter after inflation K09A; 4ml inflation; 15.2mm K08A, 6ml inflation; 16.8mm Balloon Length after inflation K09A, 4ml inflation; 20.1mm K08A, 6ml inflation; 29.2mm
Insertion and withdrawal force	Measure the insertion and withdrawal force with the 0.01m/s of test velocity. Test report#; IMT-IFWF12-01	Insertion Force IBE-10; MEAN 1.24N IBE-15; MEAN 1.65N IBE-20; MEAN 2.11N Withdrawal Force IBE-10; MEAN 1.11N IBE-15; MEAN 1.42N IBE-20; MEAN 1.79N	Insertion Force K09A; MEAN 1.08N K08A; MEAN 1.49N Withdrawal Force K09A; MEAN 0.90N K08A; MEAN 1.26N

10. Comparison to the Predicate Device

The MEDINAUT Kyphoplasty System has the same device characteristics as the predicate device, The KyphX Inflatable Bone Tamp System; intended use, materials, design and use concept, sterilization, etc. Only the technical specifications – shape, diameter and length, tension and pull out force – are slightly different.

Product Name	MEDINAUT Kyphoplasty System	KyphX Inflatable Bone Tamp
510(k)	N/A	K010246, K041454 and K981251
Manufacturer	IMEDICOM Co., Ltd.	Kyphon Inc. (Medtronic)
Indication for use	The MEDINAUT 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 PMMA bone cements indicated for percutaneous vertebral augmentation, such as kyphoplasty.	KyphX Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fracture and/or creation of a void in cancellous bone in the spine(including use during balloon kyphoplasty with KyphX HV-R™ Bone Cement), hand, tibia, radius and calcaneus.
Articles **Max. Inflation Volume** **Initial Length(mm)** **Inflated Length(mm)** **Inflated Diameter(mm)**	IBE-10, IBE-15, IBE-20 3cc, 5cc, 7cc 10, 15, 20 16, 22, 34 14, 17, 19	K08A, K09A, K13A 4cc, 4cc, 6cc 10, 15, 20 17.3, 19.7, 28.2 15.6, 14.3, 15.8
Accessories kit	Needle Pipe, Needle Pin, Wire Pin, Cannula, Expander, Spacer, Cement Pusher, Cement Filler and Guide Wire	Bone Access Needle, Introducer System, Precision Dri.., Cannula, Expander, Spacer, Cement Pusher, Cement Filler and Guide Wire
Composition of Material Balloon Tip Radiopaque Marker Expander Syringe Body Accessory Kit	 Thermoplastic Polyurethane Platinum Polycarbonate and ABS Stainless Steel and ABS	 Thermoplastic Polyurethane Platinum Polycarbonate and ABS Stainless Steel and ABS
Packaging	Pouch, Tyvek Blister Tray, Cardboard Box	Pouch, Tyvek Blister Tray, Cardboard Box
Sterilization	Gamma Sterilization	Gamma Sterilization
Biocompatibility	Meets ISO 10993	Meets ISO 10993

11. Testing and Biocompatibility

Testing performed including functional testing, such as insertion and withdrawal force, puncture force, burst and simulated use which demonstrated that the MEDINAUT Kyphoplasty System is equivalent to the predicates in specifications and performance characteristics. Biocompatibility testing confirmed that the device meets the applicable requirements of the FDA Blue Book Memorandum #95-1 entitled Use of International Standards ISO 10993 Biological Evaluation of Medical Devices Part -1: Evaluation and Testing, and is biocompatible.

12. Contraindications

Instability of posterior wall and/or pedicles
Infection
Severe bleeding
Known allergies to bone cement
Pregnancy
Fractures in which more than 68% of vertebral height is lost
Should not be used if vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon
Instability of posterior wall and/ or pedicles
Any known severe allergy to contrast media

13. Warnings

- For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur.
- Complications that may occur during a parapedicular approach include pneumothorax and bleeding
- Avoid contract between the balloon and bone cement
- The balloon component of the Vertebral Balloon may fail due to bone splinters and/or surgical tool contact
- Do not inflate the balloon until it has been fully deployed in the vertebral body. Inflating the balloon prior to full deployment may result in premature balloon failure due to contact between the balloon and the access cannula.
- Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date.
- Do not pressurize more than 350PSI.
- Do not put contrast media more than the specified Maximum volume: 10mm(3cc), 15mm(5cc), 20mm(7cc)
- Inflating the vertebral balloon beyond the maximum inflation volume may cause the balloon to rupture before reaching the maximum inflation pressure.
- Inflating the vertebral balloon beyond the maximum inflation pressure may cause the balloon to rupture before reaching the maximum inflation volume.

14. Precautions

- It is important to read the instructions for use these precautions prior to device operation.
- Use the Balloon Catheter prior to the use by date noted on the package.
- Do not use damaged products. Before use, inspect the Balloon Catheter and packaging to verify that no damage has occurred.
- Prior to use, the Balloon Catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.
- Do not use this product if you have not been properly trained. The Balloon Catheter should only be used by physicians who are trained in the techniques of bone tamp use. Physicians using the devices should be familiar with the physiology and pathology of the selected anatomy.
- The Balloon Catheter should be manipulated only while under fluoroscopic observation with radiographic equipment that provides high quality images like C-arm.
- The Balloon Catheter should only be inflated using an inflation syringe having a 20ml volume capacity.

- Only inflate the Balloon Catheter with liquid contrast medium a 60% solution is recommended.
- Follow manufacturer's instructions for contrast medium indications, usage and cautions.
- Do not use air or other gas to inflate the Balloon Catheter.
- The inflatable component of the Balloon Catheter may fail due to contact with bone splinters, bone cement and/or surgical tools.
- The inflation characteristics of the Balloon Catheter are altered by inflation inside bone.
- Do not re-sterilize and/or reuse. The Balloon Catheter is for single use only.
- Reconditioning, refurbishing, repair, modification, or resterilization of the device to enable further use is expressly prohibited.

15. Mandatory Performance Standard

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices.

16. Voluntary Standards

The MEDINAUT Kyphoplasty System was developed under the auspices of the following Standards.

Standard	Application
ISO 10993-1[2009]	Guidance on the selection of biocompatibility testing
ISO 10993-4[2002]	Applied to the biological evaluation tests for interactions with blood
ISO 10993-5[2009]	Applied to the biological evaluation tests for In Vitro cytotoxicity
ISO 10993-10[2010]	Applied to the intracutaneous reactivity test & skin sensitization test
ISO 10993-11[2006]	Applied to tests for systemic toxicity
ISO 11137-1:2006	Applied to sterilization validation
ISO 11137-2: 2012	
ISO 11137-3: 2006	
ISO 11607-1: 2006	
ISO 11607-2: 2006	
ISO 14971:2007	Applied to risk management
ISO 9001:2008	Applied to the certification of the quality management system of Medicom Co., Ltd
ISO 13485:2003	
ASTM F 1980-02	Applied to accelerated aging testing
ISO 11737-1: 2006	Applied to sterilization validation
ISO 11737-2: 2009	
ISO 11737-3: 2004	
EN 556-1:2001	

17. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification IMEDICOM Co., Ltd. submits that the MEDINAUT Kyphoplasty System in this submittal is substantially equivalent to the predicate System, the KyphX Inflatable Bone Tamp System, as described within this submittal.

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

April 4, 2014

IMEDICOM Co., Ltd.
% Ms. Priscilla Chung
Consultant/Official Correspondent
LK Consulting Group USA, Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, California 92833

Re: K133669
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: February 11, 2014
Received: February 18, 2014

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 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 133669

Device Name: MEDINAUT Kyphoplasty System

Indications for Use: The MEDINAUT 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133669