February 3, 2021

Taeyeon Medical Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, California 92620

Re: K202027/S001
Trade/Device Name: Balex Bone Expander System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG, NDN
Dated: December 23, 2020
Received: December 30, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K202027

Device Name

Balex Bone Expander System

Indications for Use *(Describe)*

The Balex Bone Expander System is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

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.

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# 510(k) Summary

(K202027)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Feb 2, 2021

**1. 510K Applicant / Submitter:**

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**2. Submission Contact Person**

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**3. Device**

- Proprietary Name: Balex Bone Expander System
- Common Name: Inflatable Bone Tamp
- Classification: Class II (21 CFR 888.1100/ 888.4540/ 888.3027)
- Product Code: HRX, HXG, NDN

**4. Predicate Device**

Kyphon Inflatable Bone Tamps (K041454) by Kyphon Inc.
Medinaut Kyphoplasty System (K133669) by Imedicom Co., Ltd.

**5. Description:**

The Balex Bone Expander System is designed to reduce compression fracture and create a void in cancellous bone in the spine. By creating a space in the operating point, the major benefits of the Balex Bone Expander System are the reduction in pain and the increase of patient`s functional abilities, which allow for the patient's return to the previous level of activity.
The Balex Bone Expander System consists of the Balloon Expander and Balloon Catheter.

They are used with Cement Dispenser System, Cement Mixer System and Syringe which are Class I, 510k exempt devices.

The Balloon Catheter consists of an inner-outer tube, inflatable balloon located at the balloon tip. The radiopaque markers located at the balloon tip end allow fluoroscopic visualization of the deflated balloon catheter during positioning. The Balloon Expander consists of a pressure gauge, compression cylinder, a connect Line and a 3 way valve. The Balloon Expander is used for inflating the balloon by rotating the plunger clockwise. The lock mechanism maintains pressure. All the components are supplied sterile and are disposable.

## 8. Indications for Use

The Balex Bone Expander System is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

## 9. Substantial Equivalence Discussion:

### 9.1. Comparison Chart

| | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| **Device Name** | **Balex Bone Expander System** | **KYPHX XPANDER INFLATABLE BONE TAMPS MODEL#KO8A,KO9A,K13A** | **MEDINAUT Kyphonplasty System** |
| **510(k) Number** | K202027 | K041454 | K133669 |
| **Product Code** | HRX, HXG, NDN | HRX | HRX, NDN |
| **Common Name** | Inflatable Bone Tamp | Inflatable Bone Tamp | Inflatable Bone Tamp |
| **Manufacturer** | TAEYEON MEDICAL Co., Ltd. | Medtronic Sofamor Danek | Imedicom Co., Ltd. |
| **Indications for Use** | The Balex Bone Expander System is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus. | The Kyphx® Inflatable Bone Tamp is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus. | The MEDINAUT Kyphonplasty 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 angmentation. This system is to be used cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty. |

| **Balloon Size** | | 10, 15, 20mm | | | 10, 15, 20mm | | | 10, 15, 20mm | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Balloon Specification** | **Model #** | TYP 0510 | TYP 0515 | TYP 0520 | K13A | K09A | K08A | IBE-10 | IBE-15 | IBE-20 |
| | **Length of Balloon** | 10.0mm | 15.0mm | 20.0mm | 10.0mm | 15.0mm | 20.0mm | 10.0mm | 15.0mm | 20.0mm |
| | **Max. Inflation Volume** | 3cc | 5cc | 7cc | 3cc | 4cc | 5cc | 3cc | 5cc | 7cc |
| | **Max. Inflated Dimension** | 15.05mm | 18.15mm | 19.49mm | 15.0mm | 5.3mm | 16.0mm | 14.1mm | 17.1mm | 19.3mm |
| | **Max. Inflated Length** | 18.25mm | 23.70mm | 31.83mm | 18.7mm | 24.4mm | 28.5mm | 16.3mm | 22.2mm | 29.4mm |
| **Bone Tamp Max. Inflation pressure** | | 350 psi | | | 700 psi | | | 350psi | | |
| **Composition of Material** | | ABS, TPU, Polycarbonate | | | ABS, TPU, STS304, Rubber | | | ABS, TPU,Platinum | | |
| **Packaging** | | Tyvek, Cardboard Box | | | Pouch, Tyvek Blister Tray, Cardboard Box | | | Pouch, Tyvek Blister Tray, Cardboard Box | | |
| **Biocompatibility** | | Meets ISO 10993 | | | Meets ISO 10993 | | | Meets ISO 10993 | | |
| **Sterilization** | | Ethylene Oxide Gas Sterilization | | | Gamma irradiation sterilization/ Ethylene Oxide Gas Sterilization | | | Gamma irradiation sterilization | | |

### 9.2. Substantial Equivalence Discussion

There are no significant differences between the subject devices and the predicate devices. The subject device has the same intended use as the identified predicate devices and they are similar in fundamental scientific technology, design, and size.
The materials used in the subject device might be different from the predicate devices; however, the biocompatibility testing results of the subject device support that the subject device is biocompatible and the performance testing results show that the subject device would perform as well as the predicate devices.

## 10. Performance Tests (Non-clinical)

- Sterilization Validation Tests in accordance with ISO 10993-7
- Shelf Life Tests in accordance with ASTM F1980, ASTM F88, ISO11737-2
- Biocompatibility Tests in accordance with ISO 10993

| No. | Items | Referenced Standard |
|---|---|---|
| 1 | Cytotoxicity Test | ISO 10993-5 |
| 2 | Maximization sensitization test | ISO-10993-10 |

| | | |
|---|---|---|
| 3 | Material-mediated pyrogenicity test | ISO10993-11 |
| 4 | Acute Systemic toxicity | ISO10993-11 |
| 5 | Intracutaneous(intadermal) Reactivity Test | ISO10993-10 |

- Performance Tests including the following test items.

| No. | Test Items |
|---|---|
| 1 | Extraction Test<br>- Non-volatile Residue, Residue on Ignition, Heavy Metals, Buffering Capacity |
| 2 | EO Gas Sterilization Residual |
| 3 | Appearance for Balloon |
| 4 | Balloon Dimensions |
| 5 | Burst Pressure (constrained and unconstrained) |
| 6 | Balloon leakage |
| 7 | Pressure gauge precision |
| 8 | Inflation and deflation time |
| 9 | Insertion force and withdrawal force |
| 10 | Tensile and tensile bond strength |
| 11 | Balloon fatigue test |

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

**11. Conclusions:**

Based on the information provided in this premarket notification, TAEYEON MEDICAL Co., Ltd. concludes that the BALEX Bone Expander System is substantially equivalent to the predicate devices as described herein in.