April 21, 2023

OK MediNet Korea Co., Ltd.
% Yang Ho Dong
Manager
Onbix Corporation
821 Samil Plaza, 14, Dogok-ro 1-gil
Gangnam-gu
Seoul, South Korea 06253

Re: K221142
Trade/Device Name: Kyphoplasty Balloon System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: April 18, 2023
Received: April 18, 2023

Dear Yang Ho Dong:

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,

Sara S. Thompson -S

Sara S. Thompson, D.V.M.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221142

Device Name
Kyphoplasty Balloon System

Indications for Use *(Describe)*

The Kyphoplasty Balloon System (KYBS) 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)

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
K221142

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

Submitter Information: OK Medinet Korea Co., Ltd.
#418, Namsung Plaza, 130, Digital-ro, Geumcheon-gu,
(08589) Seoul, Korea
T 82-2-833-4489 F 82-2-833-4432

Contact Person: Ho Dong, Yang
Onbix Corporation
#821 Samil Plaza, 14, Dogok-ro 1-gil, Gangnam-gu
Seoul, Korea (06253)
Tel: *82-2-566-3360 / Fax: *82-2-6280-3360
Email: onbix@naver.com

Date Summary Prepared: April 20, 2023

Device Information:
Trade Name(s): **Kyphoplasty Balloon System**
Classification Name: Arthroscope
Product code & regulation: HRX & 888.1100

Predicate Device Information:
K202027 Balex Bone Expander System, TAEYEON Medical Co.

Device Description:
The Kyphoplasty Balloon System (KYBS) is designed to reduce spinal compression fracture and restore sagittal alignment. The device creates a space in the vertebral body to facilitate the insertion of bone cement and using cement dispensing plunger. The KYBS components are balloon catheter, cement dispenser and balloon dilator.
The main components of the balloon catheter are the shaft, hub and the inflatable balloon located at the distal tip and inflatable balloon is covered 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.

Intended Use/ Indications for Use:
The Kyphoplasty Balloon System (KYBS) 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.

Performance properties
The device was conducted in compliance with the following Standards:

- Biocompatibility tests in accordance with ISO 10993-1, ISO-10993-4, ISO 10993-5, ISO 10993-10 for Cytotoxicity, Skin sensitization, Intracutaneous reactivity, Acute systemic toxicity, Material-mediated Pyrogen testing, and Hemolysis

- Bacterial Endotoxin Test – the device met the limit specifications of ANSI/AMMI ST72:2019
- Packaging stability tests in accordance with ISO 11607
- Device characterization and performance tests in accordance with ISO 10555-1, ISO 10555-4, ASTM F1874 and ASTM F2132

Summary of the technological characteristics compared to the predicate device
Similarity: The standard size of the balloon component is the same at 10mm, 15mm, and 20mm, the raw material used is the same as thermoplastic polyurethane (TPU), and the appearance is similar. In addition, the high-frequency welding method of the balloon part and the connection part is the same during production, the purpose of use for instability due to spinal compression fractures, and method of use, such as the method of perforating diseased parts, are similar. In addition, contrast medium, use of cannula tube for balloon insertion, balloon removal, and use of bone cement are similar between devices.
Difference: Our product balloon part is able to twist for easier insertion into the affected part of the spine compared to the predicate device.

Non-Clinical (Animal) Study performance
Not applicable

Conclusion
Kyphoplasty Balloon System is substantially equivalent to the predicate device in its intended use and technological characteristics