February 29, 2024

Ningbo HicRen Biotechnology Co., Ltd.
% Raymond Wu
Project Engineer
PureID Medical Technology Co., Ltd.
Guangzhou International Biology Island Luoxuan Blvd Guanzhou
Life Science Innovation Cntr, Bd.A 3301-3310 & 3316-3318
Guangzhou,
China

Re: K232842
Trade/Device Name: Balloon Inflation System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN
Dated: September 14, 2023
Received: September 14, 2023

Dear Raymond Wu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jesse Muir -S
Digitally signed by Jesse Muir -S
Date: 2024.02.29 13:16:15 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232842

Device Name

Balloon Inflation System

Indications for Use *(Describe)*

The Balloon Inflation System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. 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) #: K232842

510(k) Summary

Prepared on: 2024-02-27

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact Email	raq@pureglobal.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Balloon Inflation System
Common Name	Polymethylmethacrylate (PMMA) bone cement
Classification Name	Cement, Bone, Vertebroplasty
Regulation Number	888.3027
Product Code(s)	NDN, HRX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
k153296	MEDINAUT Kyphoplasty System	NDN

Device Description Summary

21 CFR 807.92(a)(4)

Balloon Inflation System is mainly used to treat vertebral compression fractures caused by osteoporosis. Puncture needles or dilators are used to establish working channels, then balloon catheters are placed along the working channels and inflation device connect to balloon catheter and control it expansion to lift the upper and lower endplates of the vertebral body, restore the height of the vertebral body, and form bone cement filling cavities.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Balloon Inflation System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the

spine. 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication of use of the device is "The Balloon Inflation System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. 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.", which is similar to the indication of use of the predicate device:"The MEDINAUT Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void incancellous bone in the spine, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. The systemis to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneousvertebral augmentation, such as kyphoplasty."

Technological Comparison

21 CFR 807.92(a)(6)

There are no significant differences between the subject devices and the predicate devices. The subject device has the similar indication for use with minor differences that does not affect the safety and efficacy of the product compared with the predicate devices. The subject device has the same balloon max inflation pressure as the identified predicate devices and they are similar in fundamental components, balloon size, composition of materials and packaging. The sterilization used in the subject device might be different from the predicate device, however, the sterility test report of balloon catheter and inflation device, and balloon inflation system examination record of EO residue show that the subject device would perform as well as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical tests of the device-the Balloon Inflation System have been performed under Good Laboratory Practices regulations (FDA, 21 CFR Part 58-Good Laboratory Practice for Nonclinical Laboratory Studies) and in accordance to standard operating procedures and a standard protocol.

- Sterilization validating testing has been performed in accordance with ISO 11135 and ISO 11138-2, 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 3 year shelf life.
- Biocompatibility tests were performed in accordance with ISO 10993-5, 10, 11, 23, and the test results supported that the subject devices are biocompatible
- Various bench tests including product size, tensile bond strength, burst pressure constrained, fatigue strength, maximum inflalted volume, balloon deflation time, burst strength unconstraint, balloon dimension after inflation, insertion and withdrawal force, range, volume, accuracy, tensile bond strength, and leakproofness were performed to evaluate the performance and the safety of the subject devices and the test results met the preset criteria.

These tests demonstrate that the device is as safe, as effective, and perform as well as the legally marketed device-the MEDINAUT Kyphoplasty System.