August 12, 2020

IZI Medical Products, LLC
Qiang Cao
Director of QA and RA
5 Easter Court, Suite J
Owings Mills, Maryland 21117

Re: K200763
Trade/Device Name: Osteo-site® Vertebral Balloon
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, NDN
Dated: June 29, 2020
Received: July 2, 2020

Dear Qiang Cao:

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.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200763

Device Name
Osteo-site® Vertebral Balloon

Indications for Use *(Describe)*
The Osteo-site® Vertebral Balloon is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for 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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Submitter

Submitter Name:	IZI Medical Products LLC
Submitter Address:	5 Easter Court, Suite J Owings Mills, MD 21131
Telephone Number:	(410) 594-9403
Fax Number:	(410) 594-0540
Contact Person:	Qiang Cao
Registration Number:	1123169

Device Name:

Trade Name:	Osteo-site® Vertebral Balloon
Common or Usual Name:	Vertebral Balloon
Primary Classification Name:	Cement, Bone Vertebroplasty (21 CFR §888.3027, Product Code NDN)
Secondary Classification Name:	Arthroscope (21 CFR §888.1100, Product Code HRX)

Predicate Devices:

- AVAMax Vertebral Balloon [K103064]
- Modified Winch Kyphoplasty (15 And 20 Mm) 11 Gauge Balloon Catheters [K172214]

Device Description

The Osteo-site® Vertebral Balloon consists of a Y-connector with luer fitting, catheter with mandrel, and a balloon with radiopaque markers. The Y-connector is adhered to a strain relief fitting which is then adhered to the proximal end of the outer shaft. The mandrel ball is placed in a socket at the proximal end of the Y-connector that is coaxial to the catheter. The distal end of the catheter is welded to the proximal end of the balloon and the distal end of the mandrel is screwed into the distal end of the balloon. This construction allows for fluid to fill from the angled section of the Y-connector, around the mandrel, and into the balloon without obstruction. The mandrel can move freely longitudinally until the ball end meets the limits of the socket at the proximal end of the Y-connector. This controls the balloon expansion longitudinally. The radiopaque markers at the distal end of the mandrel are an imaging reference of balloon placement for the user. The proximal markers are visual indication of the balloon's placement. The exterior surface of the balloon is covered by a lubricant which eases access through the introducer cannula.

Indications for use

The Osteo-site® Vertebral Balloon is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for Kyphoplasty.

Technological Characteristics

The design and technological characteristics of the predicate AVAmax balloon are substantially equivalent to the proposed Osteo-site® Vertebral Balloon.

Both the proposed and predicate device use the same technological characteristics for creation of the void within bone. Both devices use radio fluorescent markers to identify placement of the device. In both cases contrast is used to inflate a polyurethane balloon in order to compress cancellous bone within the vertebral body. Lastly, in both cases the contrast is delivered through a luer connector at the proximal end of the balloon and the contrast flows along a catheter shaft until reaching the balloon at the distal end of the assembly.

Technological Comparison			
Description	**Osteo-site® Vertebral Balloon**	**Predicate AVAmax [K103064]**	**Predicate Modified Winch [172214]**
Prescription/over the counter use	Prescription	Prescription	Prescription
Sterilization Method	EO	EO	EO
Balloon size	15mm	15mm	15mm
Max Balloon Volume	4mL	4mL	4mL
Max Inflation Pressure	400 psi	400 psi	400 psi
Siliconization	Yes	No	Yes
Packaging configuration	Tyvek sealed tray within Tyvek pouch	Tyvek sealed tray	Tyvek pouch
Markers	Platinum/Iridium	Platinum/Iridium	Platinum/Iridium
Catheter length	240mm	189mm	241mm
Balloon Material	Polyurethane	Polyurethane	Polyurethane
Catheter Material	Polyurethane	Polyurethane	Polyurethane

The design and technological characteristics of the predicate AVAmax and Modified Winch balloons are substantially equivalent to the proposed Osteo-site® Vertebral Balloon.

Performance Testing

The following testing was conducted to prove substantial equivalence with the predicate device (AVAmax Vertebral Balloon [K103064]).

Test Performed	Acceptance Criteria
Unconstrained Burst Volume	Proposed device exceeds the predicates maximum rated volume before burst failure
Constrained Burst Pressure	Proposed device exceeds the predicates maximum rated pressure while constrained
Inflated Balloon Dimensions	Proposed inflated balloon dimensions are similar to the predicate device
Deflation Time with Contrast Solution	Deflation time is similar to the predicate device of the same size and volume profile
Tensile Force Testing	Device material and bond strengths are similar to the predicate device.
Fatigue Testing	Proposed device must withstand three cycles of inflation at max psi.

No clinical testing was conducted for this submission.

Sterilization and Shelf-Life

The device will be ETO sterilized. The Sterility Assurance Level (SAL) is 10^{-6}.

The device has a shelf-life of 12 months based on an accelerated aging study.

Biocompatibility

The biocompatibility evaluation for the Osteo-site® Vertebral Balloon was conducted in accordance with ISO-10993-1, Biological Evaluation of Medical Devices. Testing included the following:

- **Cytotixicity**
- **Irritation**
- **Sensitization**
- **Pyrogenicity**
- **Systemic Toxicity**

The Osteo-site® Vertebral Balloon is considered indirect blood contacting for a duration of less than 24 hours.

Summary of Substantial Equivalence

Based on the indications for use, intended use, design, safety and performance testing, the proposed Osteo-site® Vertebral Balloon meets the requirements that are considered essential for its intended use and is substantially equivalent to the Predicate Devices, AVAmax Vertebral

Balloon [K103064] and Modified Winch Kyphoplasty (15 And 20 Mm) 11 Gauge Balloon Catheters [K172214].

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