November 8, 2019

BŌNWRx Ltd
℅ Connie Qiu
Regulatory Consultant
M Squared Associates, Inc.
575 8th Avenue, Suite 1212
New York, New York 10018

Re: K192403
Trade/Device Name: VK100® Percutaneous Vertebral Augmentation System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: August 22, 2019
Received: September 3, 2019

Dear Ms. Qiu:

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,

Laurence D. Coyne, Ph.D.
Acting 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)*
K192403

Device Name
VK100® Percutaneous Vertebral Augmentation System

Indications for Use *(Describe)*
The VK100® Percutaneous Vertebral Augmentation System is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (haemangioma), or malignant lesions (metastatic cancers, myeloma).

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) Summary

510(k) Summary as required by section 21 CFR 807.92(c)

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Device Name and Classification

Trade Name of Device: VK100®

Common or Usual Name: Percutaneous Vertebral Augmentation Device

Classification Name: Cement, Bone, Vertebroplasty
Product Code: NDN
Classification Panel: Orthopedic
Regulation Number: 21CFR Sec. 888.3027
Device Class: Class II

Substantial Equivalence

VK100® is substantially equivalent to the following medical devices in commercial distribution:

Predicate Device	**Manufacturer**	**510(k) Number**
KyphX® HV-R™ Bone Cement	Kyphon, Inc.	K041584
Reference Devices	**Manufacturer**	**510(k) Number**
Kyphon™ HV-R™ Bone Cement	Medtronic	K180700
Spine-Fix® Biomimetic Bone Cement	Teknimed S.A.	K043593
F20 Bone Cement	Teknimed S.A.	K103433
Spineplex™ Radiopaque Bone Cement	Stryker	K032945

Substantial Equivalence

VK100® has the same intended use and indications, similar technological and handling characteristics, and similar principles of operation as its predicate and reference devices. The differences between VK100® and its predicate device raise no new issues of safety or effectiveness. Performance and clinical data demonstrate that VK100® is as safe and effective as its predicate and reference devices. Thus, VK100® is substantially equivalent.

Device Description

Like the predicate devices, VK100® is provided as a two-component system with barium sulfate as a radiopacifier. VK100® is a polydimethylsiloxane material. The VK100® System consists of a cartridge containing the two VK100® material components and a dispensing system which blends the two components for injection into the injured vertebrae. The material cures *in situ* to form a non-resorbable polymer.

The VK100® material is supplied in a pre-filled cartridge:

The 2-cylinder cartridge keeps each component separate until administration, when both components are extruded through a mix element, which blends the mixture at a 1:1 ratio.

Each dose (cartridge of VK100® material) consists of:

- Reinforced Dimethyl Methylvinyl Siloxanes
- Barium Sulfate powder
- Methylhydrogensiloxane Crosslinker
- Platinum catalyst, < 0.002% as metal

Indications for Use

VK100® is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (haemangioma), or malignant lesions (metastatic cancers, myeloma).

Performance Data

Performance testing was conducted to ensure that VK100® met its design specifications and performed in a manner substantially equivalent to the predicate and reference devices. Testing included biocompatibility, material handling, mechanical, comparative testing between the predicate and reference devices, sterilization, packaging, and shelf-life validation. VK100® functioned as expected in all testing.

Biocompatibility Data

The material used in VK100® meets or exceeds the requirements of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as adopted by the US FDA in June 2016. VK100® was tested in direct comparison to predicate devices and verified as substantially equivalent, as defined by ISO-10993. Biocompatibility evaluations included cytotoxicity, sensitization, irritation, acute systemic

toxicity, pyrogenicity, genotoxicity, hemolysis, implantation, thermal properties, bacteriostasis and fungistasis, identification and quantification of degradation products, and chemical characterization of materials.

Sterilization

VK100® is sterile and non-pyrogenic. VK100® is a system consisting of sterile, single use components: a dispensing handle, cartridge, and static mix element. All of the components of the VK100® system are sterilized using traditional methods. Moist heat, Ethylene Oxide ("EO") or a combination thereof is used to sterilize the VK100® components. The sterilization method was validated using the "Overkill" method to a sterility assurance level of 10^{-6}.

Shelf Life

VK100® samples were subjected to both accelerated and real time aging and evaluated for handling and performance to confirm a two-year shelf life. The results demonstrate that the packaging was capable of withstanding the stress associated with distribution, shipping and sterilization, and that the packaging is capable of maintaining a sterile barrier for a two (2) year labeled shelf life.

Clinical Data

Clinical information demonstrates that the intended use of VK100® is substantially equivalent to predicates and while VK100® may have different technological characteristics it does not raise any different questions of safety and effectiveness and is at least as safe and effective as the predicate PMMA. Clinical data demonstrates that VK100® is substantially equivalent to predicate PMMA devices.

A radiographic evaluation of existing clinical data was performed to assess the incidence of post-procedure material extravasation and migration associated with use of VK100®. The study population included a consecutive series of 124 subjects, of which 74% were female with a mean age of 75, treated with the VK100® System. The extravasation rate for the clinical study of VK100® was 1.6%. A review of 470 publications, with 21 meeting the study requirements, demonstrated that the average extravasation rate for the predicate PMMA was 29.54%. Therefore, this study of VK100® showed that extravasation rates, and the risks of subsequent pulmonary embolism, are equivalent to those reported for PMMA in patients undergoing vertebral augmentation.

An independent review of the radiographic images was performed for all 124 subjects to identify any images suggesting migration or extravasations of VK100®. The primary safety measure for this study was the incidence or lack thereof of pulmonary emboli related to the study device or study procedure. The incidence and occurrence of extravasations was used as the primary indicator of the potential risk for a pulmonary embolus.

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