DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 12, 2017

Teknimed, SAS
% Mr. J.D. Webb
Authorized Contact Person
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K161114
Trade/Device Name: HIGH V+
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: April 10, 2017
Received: April 11, 2017

Dear Mr. Webb:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K161114

Device Name
HIGH V+

Indications for Use *(Describe)*

The HIGH V+ is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

5*10(k) Summary*
for the HIGH V+ Bone cement

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the HIGH V+.

1. GENERAL INFORMATION

Date Prepared: November 11, 2016

Trade Name: HIGH V+

Common Name: Polymethylmethacrylate (PMMA) bone cement

Classification Name: Cement, Bone, Vertebroplasty

Class: II

Product Code: NDN

CFR section: 21 CFR section 888.3027

Device panel: Orthopedic

PrimaryLegally Marketed Predicate Device: Vertecem, K090435

Secondary Legally Marketed Predicate Device: Spineplex K032945

Submitter:
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2. DEVICE DESCRIPTION

HIGH V+ is a self-hardening and ready to use Poly Methylmethacrylatebone cement with 36.4% of radiopaque agentsfor the treatment of painfulvertebral fractures based on the predicate devices Spineplex. Vertecem. It can be injected directly into the fractured vertebral body by either Vertebroplasty or Kylphoplasty procedures to relieve pain. HIGH V+ allows an excellent consolidation of the vertebral body and an effective and rapid pain relief. The HIGH V+ cement is made of two sterile components: the polymer in powder and the liquid monomer. These two components are in a double sterile packaging. Each unit contains a sterile ampoule of liquid within a blister pack and a powder within a double peelable pouch, the whole being packaged in a box.

Material:

The liquid component is mainly composed of methyl methacrylate. The major powder components are polymethylmethacrylate (PMMA), hydroxyapatite and barium sulfate.Benzoyl peroxide which initiates the polymerization is included in the polymer powder.

Function:

The HIGH V+ bone cement allows stabilization of the vertebral body and a rapid pain relief.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

HIGH V+ has similar technological characteristics as the predicate devices as shown in the detailed side by side comparison in the following table.

Device / Items	HIGH V+	Vertecem	Spineplex
Sponsor	Teknimed	Teknimed	Stryker
510(k) Number	--	K090435	K032945
Product Code	NDN	NDN	NDN
Indications for Use	[2] below table	[1] below table	[3] below table
Chemical composition			
Powder (% w/w)	20g ± 0.4g	21g ± 0.4g	20g
Polymethymethacrylate	63.1% ± 1%	43.4% ± 1%	11.5%
Methyl methacrylate styrene copolymer	-	16.1% ± 1%	57%
Benzoyl peroxide	0.5% ± 0.1%	0.5% ± 0.1%	1.5%
Barium sulfate	27.3% +2.1% - 1.9%	30% +2% -3%	30%
Hydroxyapatite	9.1% +1.9% / -2.1%	10% ± 1%	--
Liquid (% w/w)	8.6g± 0.2g	9.2 ± 0.2g	9.4g
Methylmethacrylate	98.5% ± 1%	99.3% ± 1%	97.4%

Device / Items	HIGH V+	Vertecem	Spineplex
Dimethyl-paratoluidine	1.5% ± 0.1%	0.7% ± 0.1%	2.6%
Hydroquinone	20ppm± 5ppm	20ppm± 5ppm	75ppm
Physical characteristics			
Molecular weights: Powder Cured cement	 534,511 g/mole 646,966 g/mole	 222,518 g/mole 394 552 g/mole	 --
Working phases @ 20°C	• Mixing: 0.5 min • Waiting: 3 min • Application: 9 min Setting time: 16min	• Mixing: 3 min • Waiting: 11.5 min • Application: 25 min Setting time: 30min	--
Compressive strength	81.91 MPa	80.3 MPa	--
Dynamic tension-compression mean fatigue	4,627,970±847,458 cycles @ 7Mpa	4,317,676±1,237,780 cycles @ 7Mpa	3,799,425±1,990,989 cycles @ 7Mpa
Bending strength	57.22 MPa	52.6 MPa	--
Bending modulus	3338.82	4173 MPa	--
Radiopacity	Equivalent radiopacity	Equivalent radiopacity	Equivalent radiopacity
Monomer elution testing	Increase release till 10 minutes after mixing, then stabilization	Increase release till 10 minutes after mixing, then stabilization	--
Sterilization method			
Powder	Gamma radiation (ISO 11137)	Gamma radiation (ISO 11137)	Gamma radiation (ISO 11137)
Liquid	Filtration (ISO 13408)	Filtration (ISO 13408)	Filtration (ISO 13408)
Inner Blister	Ethylene oxide (ISO 11135-1)	Ethylene oxide (ISO 11135-1)	Ethylene oxide (ISO 11135-1)

4. INTENDED USE

The HIGH V+ is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

5. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Powder morphology
- Molecular weights
- Monomer elution testing
- Viscosity vs. temperature
- Setting time vs. temperature
- Handling times
- Compressive strength
- Bending strength
- Bending modulus
- Dynamic tension-compression fatigue test
- Radiopacity
- Glass transition
- Bacterial Endotoxins Test (BET) to establish non-pyrogenicity

Test data indicate that the final properties of HIGH V+ are in compliance with the standard reference for bone cement: ISO 5833 "implants for surgery - acrylic resin cements" and are substantially equivalent to those of predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed.

7. CONCLUSIONS NONCLINICAL AND CLINICAL

This summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that HGH V+ bone cement is as safe, as effective, and perform as well as the predicate devices.