October 13, 2020

Icotec AG
% Justin Eggleton
Vice President, Spine Regulatory Affairs
Musculosketal Clinical Regulatory Affairs
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K200596
Trade/Device Name: G21 Cement, VADER® Pedicle System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: PML, NKB
Dated: August 27, 2020
Received: August 27, 2020

Dear Justin Eggleton:

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,

for Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K200596

Device Name
G21 Cement

Indications for Use *(Describe)*
When used in conjunction with the icotec VADER® Pedicle System, G21 V-Fast and V-Steady Bone Cement are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving thoracic and lumbar spine in whom life expectancy, prior to oncological treatment, is of insufficient duration to permit achievement of fusion. The fenestrated VADER® one pedicle screws 6.0 augmented with G21 V-Fast or V-Steady Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K200596

Device Name
VADER® Pedicle System

Indications for Use *(Describe)*
The VADER® Pedicle System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy, prior to oncological treatment, is of insufficient duration to permit achievement of fusion.

When used in conjunction with G21 V-Fast or V-Steady Bone Cement and PicoMix™ V and/or V-HP Gun with the icotec Cement Cannula for mixing and injection of bone cements, the fenestrated VADER® pedicle screws 6.0 are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy, prior to oncological treatment, is of insufficient duration to permit achievement of fusion. The fenestrated VADER® pedicle screws 6.0 augmented with G21 V-Fast or V-Steady Bone Cement are limited to the use at spinal levels where the structural integrity of the spine is not severely compromised.

The VADER® Pedicle System is indicated to provide the surgeon with a minimally invasive and open approach for posterior spinal surgery.

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

Device Trade Name: G21 Cement

VADER® Pedicle System

Manufacturer:
icotec ag
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9450 Altstätten
Switzerland
www.icotec-medical.com
Phone: +41 71 757.0000

Contact:
Ms. Marina Hess
CQO/Management Representative
icotec ag

Prepared by:
Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
jeggleton@mcra.com

Date Prepared: October 9, 2020

Classifications:
G21 Cement:
21 CFR §888.3027, Polymethylmethacrylate (PMMA) Bone Cement

VADER® Pedicle System:
21 CFR §888.3070, Thoracolumbosacral Pedicle Screw System

Class: II

Product Codes: PML, NKB

Indications for Use:

G21 Cement:
When used in conjunction with the icotec VADER® Pedicle System, G21 V-Fast and V-Steady Bone Cement are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving thoracic and lumbar spine in whom life expectancy, prior to oncological treatment, is of insufficient duration to permit achievement of fusion. The fenestrated VADER® one pedicle screws 6.0 augmented with G21 V-Fast or V-Steady Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

VADER® Pedicle System
The VADER® Pedicle System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy, prior to oncological treatment, is of insufficient duration to permit achievement of fusion.

When used in conjunction with G21 V-Fast or V-Steady Bone Cement and PicoMix™ V and/or V-HP Gun with the icotec Cement Cannula for mixing and injection of bone cements, the fenestrated VADER® pedicle screws 6.0 are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy, prior to oncological treatment, is of insufficient duration to permit achievement of fusion. The fenestrated VADER® pedicle screws 6.0 augmented with G21 V-Fast or V-Steady Bone Cement are limited to the use at spinal levels where the structural integrity of the spine is not severely compromised.

The VADER® Pedicle System is indicated to provide the surgeon with a minimally invasive and open approach for posterior spinal surgery.

Device Description:
The purpose if this Traditional 510(k) is to seek marketing clearance for the G21 Cement (V-Steady and V-Fast Bone Cements) to be used with the VADER® Pedicle System and to seek clearance for the VADER® Pedicle System.

V- Steady and V-Fast are polymethylmethacrylate (PMMA) based bone cements formulated to perform percutaneous vertebral augmentation procedures, such as vertebroplasty or kyphoplasty. Bone cements are self-curing systems consisting of liquid and powder components:

- The powder component is constituted of PMMA beads shaped particles containing the initiator benzoyl peroxide required for starting initiating the cement curing. The radiopacifier agent, zirconium dioxide, is necessary for the cement visibility under radiographs but it does not take part of the curing process (radical polymerization).

- The liquid component comprises the monomer, methylmemethylmethacrylate (MMA); dimethyl-para-toluidine (DMPT) as polymerization accelerator and hydroquinone (HQ) as stabilizer to prevent polymerization of the liquid during storage.

The specific content of PMMA and benzoyl peroxide is slightly different between the two cements conferring upon them specific properties. V-Steady bone cement has an immediate development of viscosity and thus it is a high viscosity cement that maintains its properties throughout the useful working time. The V-Fast has a low initial viscosity and a long working time allowing to work extremely carefully especially when a good time margin before polymerization is required. Both the liquid and powder components are supplied sterile. The sterile-filtered monomer component is supplied in an amber glass ampoule (10 ml) and comes in a blister pack sterilized by ethylene oxide. The polymer powder component is supplied in a double sterile packaging.

The sterilization process is ethylene oxide and it has been properly validated. Preparation and application procedures of the subject devices are detailed within the labeling as Mixing Phase, Waiting Phase, Application Phase, Setting/Hardening Phase.

The VADER® Pedicle System is a posterior pedicle system manufactured from Carbon/PEEK using a proprietary manufacturing process and comprised of polyaxial pedicle screws and curved, straight and J-rods as well as polyaxial, cannulated, fenestrated pedicle screws. The VADER® Pedicle System can be used for single or multiple level fixations in the non-cervical spine.

Primary Predicate Devices:
Steady and V-Fast (K150408)

Additional Predicate Devices:

- icotec VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 (K190545)
- icotec Pedicle System (K151977)
- Blackstone Pedicle Screw System (K082797)
- Corelink Tiger Spine System (K113058)
- CarboFix Pedicle Screw System (K182377)
- CarboClear Fenestrated Pedicle Screws, High V+ Bone Cement (K190526)

Performance Testing Summary:
The testing of the VADER® Pedicle System includes:

- ASTM F543 Screw Testing
- ASTM F1717 Pedicle Screw System Testing
- ASTM F1798 Flexion Bending and Torsional Gripping
- ASTM F1877 Particle Analysis of Post-Fatigue Samples
- G-21 Cement injection properties with icotec fenestrated screws
- Biocompatibility Assessment
- Clinical Data

Substantial Equivalence:
The subject devices were demonstrated to be substantially equivalent to predicates cited in the table above with respect to indications, design, materials, function, manufacturing, and performance. The non-clinical tests performed by the company include static and dynamic compression per ASTM F1717 and screw testing per ASTM F543 and ASTM F1798. The results of the performed tests demonstrate that the VADER® Pedicle System is substantially equivalent to legally marketed predicate devices.

Conclusion:
The purpose of the traditional 510(k) is to receive regulatory clearance for the G21 Cement (V-Steady and V-Fast Bone Cements) to be used with the VADER® Pedicle System and to seek clearance for the VADER® Pedicle System and to introduce the VADER® Pedicle System to interstate commerce. Substantial equivalence has been demonstrated to the cited predicate device.