January 9, 2023

icotec ag
% Justin Eggleton
Vice President, Spine Regulatory Affairs
Mcra, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K222789
Trade/Device Name: VADER® Pedicle System, G21 Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: PML, NKB
Dated: December 12, 2022
Received: December 12, 2022

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,

Anne D. Talley -S 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222789

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.

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:

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222789

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® pedicle screws 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)

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510(k) Premarket Notification

5. 510(k) Summary

Device Trade Name:	VADER® Pedicle System, G21 Cement
Manufacturer:	icotec ag Industriestrasse 12 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 803 7th Street NW Washington, DC 20001 jeggleton@mcra.com
Date Prepared:	September 15, 2022
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:

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 are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time. The fenestrated VADER® pedicle screws 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.

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

510(k) Premarket Notification

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® pedicle screws 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.

Device Description:

The purpose of this Traditional 510(k) is to seek marketing clearance for the VADER® Pedicle System. 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, S-rods 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 Device:

The subject icotec VADER® Pedicle System is substantially equivalent to the icotec VADER® Pedicle System, G21 V-Fast and V-Steady Bone Cement (K200596).

Additional Predicate Devices

- VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 (K190545)
- icotec Pedicle System (K151977)

Performance Testing Summary:

Mechanical testing was performed per ASTM F1717 (static/dynamic compression bending, static torsion) ASTM F1798 (flexion, axial gripping, torsional gripping), ASTM F543/F2193 (screw driving torque test) and cement injection testing. Results of testing indicate the addition of the Ø4.5 mm screws and 300 mm spinal rods are substantially equivalent to the predicate device.

Substantial Equivalence:

The subject devices were demonstrated to be substantially equivalent to predicates cited in the section above with respect to indications, design, materials, function, manufacturing, and performance. The results of the performed tests demonstrate that the VADER® Pedicle System is substantially equivalent to legally marketed predicate devices.

Conclusion:

The icotec VADER® Pedicle System inclusive of Ø4.5 mm screws and 300 mm spinal rods are substantially equivalent to the cited predicate devices with respect to indication for use, design, function, material, and performance.