February 27, 2025

icotec ag
% Justin Eggleton
VP, Musculoskeletal Regulatory Affairs
MRCA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K242900
Trade/Device Name: VADER® Pedicle System and VADER®one Pedicle System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, PML
Dated: January 17, 2025
Received: January 17, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin O'neill -S

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)*
K242900

Device Name
VADER® Pedicle System, VADER®one Pedicle System

Indications for Use *(Describe)*
The 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 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 augmented with G21V-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 intended to stabilize the thoracic and/or lumbar spine as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

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

VADER®one Pedicle System:
The VADER ®one 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.

The VADER®one 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.

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"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."

510(k) Summary

Device Trade Name:	VADER® Pedicle System, VADER®one Pedicle System
Manufacturer:	icotec ag Industriestrasse 12 9450 Altstaetten Switzerland www.icotec-medical.com
Contact:	Justin Eggleton Vice President, Head of Musculoskeletal Regulatory Affairs MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Phone: 202.552.5804 jeggleton@mcra.com
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	February 21, 2025
Classifications:	21 CFR §888.3070, Thoracolumbosacral pedicle screw system 21 CFR §888.3027, Polymethylmethacrylate (PMMA) bone cement
Class:	II
Product Codes:	NKB, PML
Primary Predicate:	VADER® Pedicle System (K232628)
Additional Predicate:	VADER®one Pedicle System MIS (K193423) Tiger® Spine System (K133369)

Indications For Use:
The 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 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 augmented with G21V-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 intended to stabilize the thoracic and/or lumbar spine as an adjunct to fusion in patients with spinal infection (e.g., spondylodiscitis, osteomyelitis) and spinal instability due to infection, surgical debridement, or decompression.

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

VADER®one Pedicle System:
The VADER ®one 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.

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

Device Description:
The purpose of this Traditional 510(k) is to seek marketing clearance for the VADER® Pedicle System and VADER®one Pedicle System with additional connector components. The VADER® Pedicle System and VADER®one Pedicle System are posterior pedicle systems manufactured from Carbon/PEEK using a proprietary manufacturing process and comprised of:

- Polyaxial cannulated, fenestrated pedicle screws,
- Polyaxial, cannulated, pedicle screws,
- Curved, straight, S-rods, J-rods,
- Connectors

The VADER® Pedicle System and VADER®one Pedicle System can be used for single or multiple level fixations in the non-cervical spine.

Predicate Device:
icotec ag submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, VADER® Pedicle System and VADER®one Pedicle System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: VADER® Pedicle System (K232628)

Additional Predicate: VADER®one Pedicle System MIS (K193423)
Tiger® Spine System (K133369)

Performance Testing Summary:
Bench testing consisting of static axial gripping capacity testing and static torque gripping capacity per ASTM 1798 and dynamic compression bending per ASTM F1717 was successfully completed.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate cited in the section above with respect to indications, design, materials, function, manufacturing, and performance. The VADER® Pedicle System and the VADER®one Pedicle System are substantially equivalent to the legally marketed predicate device.

Conclusion:
The icotec VADER® Pedicle System and the icotec VADER®one Pedicle System are substantially equivalent to the cited predicate device with respect to indications for use, design, function, material, and performance.