February 26, 2024

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

Re: K232628
Trade/Device Name: VADER® Pedicle System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, PML
Dated: January 26, 2024
Received: January 26, 2024

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.

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)*
K232628

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 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 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.

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.

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510(k) Summary

Device Trade Name: VADER® Pedicle System

Manufacturer:
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Contact:
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Date Prepared: February 22, 2023

Classifications: 21 CFR §888.3070, Thoracolumbosacral pedicle screw system
21 CFR §888.3027, Polymethylmethacrylate (PMMA) bone cement

Class: II

Product Codes: NKB, PML

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 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.

Device Description:
The purpose of this Traditional 510(k) is to seek marketing clearance for the VADER® Pedicle System with expanded indications for use. 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 (K222789).

Performance Testing Summary:
Clinical data was presented to support the expanded indications for use. The clinical data provided supports a substantially equivalent safety and effectiveness profile for the use of thoracolumbosacral pedicle screw instrumentation for the indications for use. However, the provided clinical data did not support that the specific material or unique technological characteristics of the subject device components provides additional benefit relative to other thoracolumbosacral pedicle screw instrumentation for the indications for use related to infection.

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 VADER® Pedicle System is substantially equivalent to the legally marketed predicate device.

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