June 20, 2019

icotec ag
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K190545
Trade/Device Name: VADER® one Pedicle System MIS and LightMore® Pedicle System 6.0
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: May 24, 2019
Received: May 28, 2019

Dear Mr. 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,

Ronald P. Jean, Ph.D.
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)*
K190545

Device Name
VADER® one Pedicle System MIS and LightMore® Pedicle System 6.0

Indications for Use *(Describe)*
The VADER® one Pedicle System MIS and LightMore® Pedicle System 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 is of insufficient duration to permit achievement of fusion.

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

The LightMore® Pedicle System 6.0 is indicated to provide the surgeon with an 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.

510(k) Summary

Device Trade Name:	VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0
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 Senior Director, Spine Regulatory Affairs MCRA, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 jeggleton@mcra.com
Date Prepared:	March 1, 2019
Classifications:	21 CFR §888.3070, Pedicle screw spinal system
Class:	II
Product Codes:	NKB

Indications for Use:
The VADER®one Pedicle System MIS and LightMore® Pedicle System 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 is of insufficient duration to permit achievement of fusion

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

The LightMore® Pedicle System 6.0 is indicated to provide the surgeon with an open approach for posterior spinal surgery.

Device Description:
The purpose of this Traditional 510(k) is to seek marketing clearance for the VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0. The VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 are posterior pedicle systems manufactured from Carbon/PEEK using a proprietary manufacturing process and comprised of polyaxial pedicle screws and curved, straight and J-rods. The VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 can be used for single or multiple level fixations in the non-cervical spine.

Primary Predicate Device:
The VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 are substantially equivalent to the CarboFix CarboClear Pedicle System (K182377).

Additional Predicate Devices:
The VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 are substantially equivalent to additional predicate devices:

- icotec Pedicle System (K151977)
- Blackstone Pedicle Screw System (K082797)
- Corelink Tiger Spine System (K113058)

Reference Device:
The subject 510(k) references the icotec Interbody Cage System (K172480) since it has the same BlackArmor® material, surface coating (Ti-iT®), and the device is used in the same anatomical area.

Performance Testing Summary:
The testing of the VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0includes:

- ASTM F543 Screw Testing
- ASTM F1717 Pedicle Screw System Testing
- ASTM F1798 Flexion Bending and Torsional Gripping
- 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®one Pedicle System MIS and LightMore® Pedicle System 6.0 are substantially equivalent to legally marketed predicate devices.

Conclusion:

The purpose of the traditional 510(k) is to receive regulatory clearance to introduce the VADER®one Pedicle System MIS and LightMore® Pedicle System 6.0 to interstate commerce. Substantial equivalence has been demonstrated to the cited predicate devices.