September 27, 2023

icotec ag
% Justin Eggleton
VP, Spine Regulatory Affairs
MCRA, LLC
803 7th Street North West
Washington, District of Columbia 20001

Re: K230861
Trade/Device Name: VADER® Pedicle System Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 29, 2023
Received: March 29, 2023

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K230861

Device Name
VADER® Pedicle System Navigated Instruments

Indications for Use *(Describe)*
icotec Navigation Instruments are intended to be used during the preparation and placement of FDA-cleared icotec pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. These instruments are designed for use with stereotactic navigation system Medtronic StealthStation®, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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 – K230861

Device Trade Name: VADER® Pedicle System Navigated Instruments

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Date Prepared: June 27, 2023

Classifications: 21 CFR §882.4560, Stereotaxic instrument

Class: II

Product Codes: OLO

Indications For Use:
icotec Navigation Instruments are intended to be used during the preparation and placement of FDA-cleared icotec pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. These instruments are designed for use with stereotactic navigation system Medtronic StealthStation®, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Device Description:
The purpose of this Traditional 510(k) is to seek marketing clearance for the VADER® Pedicle System Navigated Instruments.

icotec's VADER® Pedicle System Navigated Instruments are reusable instruments used for the preparation and placement of FDA-cleared icotec pedicle screws during spinal surgery to assist

the surgeon in precisely locating anatomical structures. These instruments are designed for use with navigation system Medtronic StealthStation®, in combination with the Medtronic NavLock™ tracker and Medtronic SureTrak®II clamps and arrays.

The VADER® Pedicle System Navigated Instruments include awls, probes, taps, drivers and adapters. The VADER® Pedicle System Navigated Instruments are to be used with the FDA-cleared icotec pedicle screws cleared under K222789, K200596, K193423 and K190545.

Primary Predicate Device:
The subject VADER® Pedicle System Navigated Instruments are substantially equivalent to the VERTICALE® Navigation Instruments (K223649).

Reference Device:
The 510(k) submission referenced the FDA-cleared icotec pedicle screws cleared under K222789, K200596, K193423 and K190545 since the subject Navigation instruments are designed solely for use with these devices.

Performance Testing Summary:
The performance evaluation included a one-to-one dimensional comparison to demonstrate substantially equivalent geometry that is critical to navigation accuracy. Testing, including anatomical and navigated simulated use and accuracy and reliability testing, has been conducted to verify that the VADER® Pedicle System Navigated Instruments are appropriate for their intended use, to ensure functionality, accuracy and compatibility with the Medtronic StealthStation® System using the NavLock™ tracker and SureTrak®II clamps and arrays, and to demonstrate substantial equivalence to the predicate instruments.

Substantial Equivalence:
The subject devices were demonstrated to be substantially equivalent to the predicate device cited in the section above with respect to indications, design, and performance. The performance testing results demonstrate that the VADER® Pedicle System Navigated Instruments are substantially equivalent to legally marketed predicate devices.

Conclusion:
The VADER® Pedicle System Navigated Instruments are substantially equivalent to the cited predicate device with respect to indication for use, design, and performance.