October 21, 2020

Benvenue Medical, Inc.
% Justin Eggleston
Vice President, Spine Regulatory Affairs
Mcra, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K201427
Trade/Device Name: Trivergent Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 25, 2020
Received: September 25, 2020

Dear Justin Eggleston:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201427

Device Name
Trivergent Spinal Fixation System

Indications for Use *(Describe)*
The Trivergent Spinal Fixation System is intended to provide immobilization and stabilization of a single spinal segment in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of lumbar and sacral spine from L2-S1: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spinal stenosis; pseudoarthrosis; and failed previous fusion.

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.

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510(k) Summary

Device Trade Name: Trivergent Spinal Fixation System

Manufacturer:
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Date Prepared: October 21, 2020

Classification Names:
21 CFR §888.3070
Thoracolumbosacral pedicle screw system

Class: II
Product Codes: NKB

Primary Predicate: Genesys Spine, TiLock2 Spinal System (K171838)

Reference Devices:
Spinal Simplicity, Spinous Process Fusion Plate (K140046)
PMT Facet Screw, Providence Medical Technology, Inc. (K183589)

Indications for Use:

The Trivergent Spinal Fixation System is intended to provide immobilization and stabilization of a single spinal segment in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of lumbar and sacral spine from L2-S1: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spinal stenosis; pseudoarthrosis; and failed previous fusion.

Device Description:
The Trivergent Spinal Fixation System is a pedicle screw system intended to stabilize and immobilize the L2-S1 spinal segments as an adjunct to fusion. The system includes a variety of screws and plates along with guides, guidewires, drills, drivers, handles, and taps.

The Trivergent Spinal Fixation System plates and screws are available in a variety of geometries to accommodate various patient anatomies. The Trivergent screws come in lengths from 45mm to 60mm, and the Trivergent plates come in angles from 60° to 75°.

The Trivergent Spinal Fixation System implants and instruments are provided non-sterile and are to be sterilized by the end user.

The Trivergent Spinal Fixation System implants are machined from Ti-6Al-4V ELI per ASTM F136.

Performance Testing Summary:
The following bench testing was performed on the Trivergent Spinal Fixation System:

Static Compression Testing	-	ASTM F1717-18
Static Torsion Testing	-	ASTM F1717-18
Compression Fatigue Testing	-	ASTM F1717-18
Cadaver Usability Study		
Biocompatibility	-	ISO 10993-1

In summary, bench testing of the Trivergent Spinal Fixation System indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

Substantial Equivalence Summary:
Comparative information presented in the 510(k) supports the substantial equivalence of the Trivergent Spinal Fixation System to its predicate devices. The subject device was shown to have the same technological characteristics through comparisons in indications, intended use, design, material composition, range of sizes, function, and performance as compared to its predicate devices.

Conclusion:
The information and performance data demonstrate that the device is as safe, as effective, and performs as well as or better than the primary predicate device. This 510(k) was submitted on behalf of the Trivergent Spinal Fixation System has shown to be substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing, and comparison to predicate devices.