February 28, 2023

Voom Medical Devices, Inc.
℅ Morgan Hill
Senior Project Engineer
Jalex Medical
27865 Clemens Road Suite 3
Westlake, Ohio 44145

Re: K223392
Trade/Device Name: REVCON™ Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 7, 2022
Received: November 8, 2022

Dear Morgan Hill:

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,

Jesse Muir -S

For: 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)*

K223392

Device Name
REVCON™ Screw System

Indications for Use *(Describe)*

The REVCON™ Screw System is indicated for fixation of bone surgery involving reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis.

The REVCON™ Screw System is not intended for spinal use.

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

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the REVCON™ Screw System.

Submitted By: Voom Medical Devices, Inc.
800A 5th Ave, #403
New York, NY 10065

Date: 28FEB2023

Contact Person: Morgan Hill, Senior Project Engineer
Contact Telephone: (440) 222-5414
Contact Fax: (440) 933-7839

Device Trade Name: REVCON™ Screw System

Common Name: Screw, Fixation, Bone
Device Classification Name: 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: HWC

Primary Predicate Device: Wright Medical MICA™ Screw System (K162353)

Additional Predicates: N/A

Device Description:

The REVCON™ Screws are intended for use in bone reconstruction, osteotomy, arthrodesis, fracture repair, and fracture fixation of bones appropriate for the size of the device, to allow surgeons to perform a bunion osteotomy and fixation of the osteotomy with a minimally surgical technique. The REVCON™ Screw System contains fully threaded, cannulated screws offered in a variety of diameters and lengths. The screws are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI) as per ASTM F136 and are provided non-sterile for end user sterilization.

Indications for Use:

The REVCON™ Screw System is indicated for fixation of bone surgery involving reconstruction. Examples include:
• Mono or Bi-Cortical osteotomies in the foot or hand
• Distal or Proximal metatarsal or metacarpal osteotomies
• Weil osteotomy
• Fusion of the first metatarsophalangeal joint and interphalangeal joint
• Fixation of osteotomies for Hallux Valgus treatment
• Akin type osteotomy

• Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
• Calcaneus/cuboid arthrodesis
• Talar/navicular arthrodesis.

The REVCON™ Screw System is not intended for spinal use.

Summary of Technological Characteristics:

The REVCON™ Screw System is fabricated from titanium alloy per ASTM F136, and the design features for the screw system are similar to the MICA™ Screw System predicate device, including dimensions, shape, and sizes.

Performance Data – Nonclinical:

Substantial equivalence is supported by the results of mechanical testing including engineering analysis of torsional strength, driving torque, and axial pullout strength testing as per ASTM F543, *Standard Specification and Test Methods for Metallic Medical Bone Screws* and the FDA Guidance: *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*).

Table 6.1. Mechanical Testing Program for REVCON™ Screw System

Verification Method	Results
Torsional Testing	Acceptable
Driving Torque: *-Insertion Torque* *-Removal Torque*	Acceptable
Axial Pullout Strength	Acceptable

Testing according to the applicable ASTM standards demonstrated that the REVCON™ Screw System met all performance based requirements and acceptance criteria to support safety and effectiveness, and is considered substantially equivalent to the predicate device.

Biocompatibility:

Biocompatibility evaluation was performed as per ISO 10993-1 to evaluate the biological safety of the REVCON™ Screw System according to the FDA Guidance: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*". The REVCON™ Screw System is categorized as an implanted medical device, principally contacting bone and tissue, with duration of contact exceeding 30 days (long-term contact). The REVCON™ bone screws are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F136, and this material is recognized by the FDA and cleared for implantation. All patient contacting instrumentation for this device is manufactured from medical grade stainless steel and is specified to be cleaned/passivated as per ASTM A967. Based on the materials, manufacturing methods, and cleaning processes used to produce the REVCON™ system, it was determined that the biocompatibility of the subject device was substantially equivalent to the predicate device.

Performance Data – Clinical:

Clinical testing is not required and therefore not conducted as part of this submission.

Substantial Equivalence:

The REVCON™ Screw System has the same intended use and fundamental scientific technology as the Wright Medical MICA™ Screw System (K162353) primary predicate device. Both devices compare similarly in:

- Design features and instrumentation
- Intended use and indications for use
- Material composition
- Dimensions
- Function
- Sterilization methods

The potential impact on substantial equivalence of each technological difference was addressed through risk analysis and verification and validation testing. Any differences between the REVCON™ Screw System and the predicate device do not raise any questions of safety and effectiveness.

Conclusion:

The REVCON™ Screw System is as safe and effective as its predicate device, as it has similar intended use, indication for use, material composition, design features, manufacturing method, sterilization method, performance requirements and principles of operation as the primary predicate device (K162353). The design differences do not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. Non-clinical testing demonstrates that the REVCON™ Screw System is as safe and effective as the predicate, therefore is substantially equivalent.