June 12, 2023

GM Dos Reis Industria e Comercio Ltda
Guilherme Esteves Pontes
Regulatory Affairs Analyst
Avenida Pierre Simon de La Place 600
Campinas, SP 13069-320
Brazil

Re: K230397
Trade/Device Name: Cut Screw - Percutaneous Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 11, 2023
Received: May 11, 2023

Dear Guilherme Esteves Pontes:

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,

Tejen D. Soni -S
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For
Shumaya Ali, MPH
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)*
K230397

Device Name
Cut Screw - Percutaneous Compression Screw

Indications for Use *(Describe)*
Cut Screw - Percutaneous Compression Screw are single use devices indicated for fixing and stabilizing the bones of the mid foot, metatarsal and phalanges of the foot using an appropriate relation bone-screw size.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter:

GM Dos Reis Industria e Comercio Ltda
Avenida Pierre Simon de La Place 600
Campinas, São Paulo, Brazil 13069-320
Guilherme Esteves Pontes
Regulatory Affairs Analyst
Telephone: +55 (19) 3765-9900
Email: guilherme.qualidade@gmreis.com.br
Date prepared: February 06, 2023

II. Device Name:

Trade Name:	Cut Screw - Percutaneous Compression Screw
Common Name:	Screw, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	II
Product Codes:	HWC
Regulation Number:	21 CFR 888.3040

III. Predicate Devices:

Legally marketed devices to which we are claiming "Substantial Equivalence" are the following:

Nexis® osteosynthesis compressive screws (K143229) (Primary predicate device).

Mini and Micro Fragments Reconstruction System - GMReis (GMReis, K182718) (Reference device).

EXPERT - Joint Fixation System - GMReis (GMReis, K200332) (Reference Device).

IV. Device Description:

The purpose of this submission is to obtain marketing clearance for the Cut Screw - Percutaneous Compression Screw.

The Cut Screw - Percutaneous Compression Screw is a screw for bone synthesis, with a hole in the center in order to allow the passage of the guide wire, thus facilitating its placement, as the surgeon is able to verify the positioning of the screw through the radiological image of the guide wire before its placement. In addition, the Cut Screw - Percutaneous Compression Screw, provides anatomical reduction, stable fixation, and preservation of blood supply by using a percutaneous incision.

The screws have a hexagonal connection for a wrench. They are found in a variety of diameters to meet the range of anatomies of the patients, are presented in Titanium Alloy according to the standard ASTM F136, it could be provided in sterile condition sterilized by Ethylene Oxide or non-sterile condition to end user and must be cleaned, and steam sterilized before use.

The devices must only be used by qualified surgeons mastering the surgical technique, having been trained and qualified in orthopedic surgeries.

V. Statement of Indications for Use of the Device:

Cut Screw - Percutaneous Compression Screw are single use devices indicated for fixing and stabilizing the bones of the mid foot, metatarsal and phalanges of the foot using an appropriate relation bone-screw size.

VI. Comparison of Technological Characteristics with The Predicate Device:

The subject device is substantially equivalent in indications and design principles to the following predicate device:

K143229 - Nexis® osteosynthesis compressive screws - Novastep

The subject and predicate devices have equivalent intended use and equivalent technological characteristics. The subject and predicate devices are all manufactured from identical materials and share equivalent design characteristics. The subject and predicate devices encompass equivalent physical dimensions. Any difference in the technological characteristics do not raise new issues of safety or efficacy.

Biocompatibility of the subject devices are supported by the reference device K182718. The performance of the subject device screws was compared with the specific guidance *"Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway"* and are demonstrated through mechanical testing according to ASTM F543. No clinical data were included in this submission.

The subject devices could be provided sterile by Ethylene Oxide method or could be provided non-sterile to be sterilized at the end-user and have no expiration date defined. Both sterilization method was validated according to the applicable standards. Pyrogenicity monitoring according to AAMI/ANSI ST72 meeting pyrogen limit specifications.

VII. Performance Data:

The Non-clinical tests performed and the Recognized Consensus Standards to which the Cut Screw - Percutaneous Compression Screw have been tested are specifically the following:

- Torsional Properties of Metallic Bone Screws per ASTM F543
- Driving Torque of Medical Bone Screws per ASTM F543
- Axial Pullout Strength of Medical Bone Screws per ASTM F543

The test results demonstrate that the subject device presents safety and efficacy in terms of mechanical properties.

VIII. Conclusions:

As was established in this submission, the subject Cut Screw - Percutaneous Compression Screw are substantially equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics, intended use, indications for use, material composition, anatomical region, multiple sizes, and basic design features compared to its predicate devices. Any differences between the Cut Screw - Percutaneous Compression Screw and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.

MATRIZ | HEADQUARTER
Av. Pierre Simon de Laplace, 600 | Lote 3 Quadra F | Quarteirão 9677
Techno Park | Campinas/SP | 13069-320
Fone: +55 19 3765 9900 | gmreis@gmreis.com.br | GMReis.com.br