April 27, 2022

ExsoMed Corp.
Reinhold Toerek
Director of QA/RA
135 Columbia, Suite 201
Aliso Viejo, California 92656

Re: K220892
Trade/Device Name: ExsoMed INnate Nano™ Lag 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: March 21, 2022
Received: March 28, 2022

Dear Reinhold Toerek:

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, 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)*
K220892

Device Name
ExsoMed INnate Nano™ Lag Screw System

Indications for Use *(Describe)*
The ExsoMed INnate Nano™ Lag Screw System is intended for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

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

Manufacturer: ExsoMed, Corp.
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Contact: Mr. Reinhold Toerek
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Prepared By: Mr. Reinhold Toerek
Director of Regulatory & Quality
Phone: (855) 397-6633
rtoerek@exsomed.com

Date Prepared: March 21, 2022

Device Trade Name: ExsoMed INnate Nano™ Lag Screw System

Common Name: Screw, Fixation, Bone

Classification: 21 CFR §888.3040 – Smooth or Threaded Metallic Bone Fixation Fastener
Class II

Product Codes: HWC

Indications for Use: The ExsoMed INnate Nano™ Lag Screw System is intended for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

Device Description: The purpose of this Special 510(k) is to add additional sizes and geometry to InFrame™ Cannulated Fixation System. The ExsoMed INnate Nano Lag Screw System includes

	cannulated stainless screws with a diameter of 1.5mm and lengths ranging from 6 mm to 26 mm.
Predicate Devices:	ExsoMed InFrame Cannulated Fixation System (K201430)
Technology Comparison and Non-Clinical Performance Testing	The ExsoMed Innate Nano Lag Screw is similar to the predicate (existing device) in that it is manufactured from similar materials and includes similar lengths, diameters and thread profiles. There are differences in geometry and packaging configuration. The information summarized in the Design Control Activities Summary demonstrates that the additional sizes meet the predetermined acceptance criteria for the verification activities. Testing, according to ASTM F543, and engineering analysis were used to evaluate the mechanical strength, screw fixation performance, and screw usability performance of the ExsoMed INnate Nano Lag Screw System implants.
Conclusion	The ExsoMed INnate Nano Lag Screw System is equivalent to the predicate devices with respect to intended use, materials, design, method of fixation, and performance characteristics. All results demonstrated that the ExsoMed INnate Nano Lag Screw System performs similarly to the predicate device and is substantially equivalent.