June 20, 2020

ExsoMed, Corp.
% Patricia Kontoudis
Specialist, Regulatory Affairs
Regulatory and Quality Solutions, LLC
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K201430
Trade/Device Name: InFrame™ Cannulated Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 28, 2020
Received: June 1, 2020

Dear Patricia Kontoudis:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201430

Device Name

InFrame™ Cannulated Fixation System

Indications for Use *(Describe)*

The ExsoMed InFrame™ Cannulated Fixation 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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4. 510(k) Summary

Manufacturer: ExsoMed, Corp.
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Date Prepared: May 28, 2020

Device Trade Name: InFrame™ Cannulated Fixation 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 InFrame™ Cannulated Fixation 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 to INnate™ Cannulated Screw System. The InFrame™ Cannulated

	Fixation System includes cannulated stainless screws with a diameter of 2.0 mm and lengths ranging from 10 mm to 50 mm.
Predicate Devices:	ExsoMed ITN Cannulated Screw System (K171558) **(Primary)** INnate Cannulated Screw System (K183603) GEO Bone Screw System (K161904)
Technology Comparison and Non-Clinical Performance Testing:	The ExsoMed InFrame™ Cannulated Fixation System has differing specific geometry from the predicates but is manufactured from similar materials and has similar lengths, diameters and thread profiles as the predicate bone screws. The information summarized in the Design Control Activities Summary demonstrates that the additional sizes meet the pre-determined 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 InFrame™ Cannulated Fixation System implants.
Conclusion:	InFrame™ Cannulated Fixation 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 InFrame™ Cannulated Fixation System performs similarly to the predicate device and is substantially equivalent.