March 12, 2019

Exsomed Corporation
Moira Barton-Varty
Director Regulatory Affairs and Quality Assurance
7227 N. 16th Street, Suite 245
Phoenix, Arizona 85020

Re: K183603
Trade/Device Name: INnate Cannulated 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: February 22, 2019
Received: February 27, 2019

Dear Moira Barton-Varty:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K183603

Device Name

INnate Cannulated Screw System

Indications for Use *(Describe)*

The ExsoMed INnate Cannulated 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

This 510(k) Summary is presented in compliance with 21 CFR 807.92

SUBMITTER

ExsoMed Corporation
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Phoenix, Arizona 85020

CONTACT PERSON

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510(k) SUMMARY PREPARATION DATE

December 3, 2018

DEVICE NAME AND CLASSIFICATION

Trade Name: ExsoMed INnate 3.6mm Cannulated Screw System
Common Name: Screw, Fixation, Bone
Classification Name: Smooth or threaded metallic bone fixation fastener
Classification: 21 CFR 888.3040
Classification: Class II
Product Code: HWC

PREDICATE DEVICES

Primary Predicate:
ExsoMed™ ITN Cannulated Screw System
K Number: K171558
Clearance Date: 09/01/17

Secondary Predicate:
Synthes 3.0mm Headless Compression Screws
K Number: K050636
Clearance Date: 04/21/2005

PURPOSE OF THIS SUBMISSION

This Special 510(k) premarket notification is submitted to obtain clearance for a line expansion to the INnate Cannulated Screw System which was originally cleared as the ITN Cannulated Screw System under K171558.

DEVICE DESCRIPTION

The ExsoMed INnate Cannulated Screw System is a stainless-steel bone screw system designed for bone fixation. The INnate system screws are cannulated and feature a headless design that allows for the screw to be countersunk below the surface of the bone. The system is provided sterile.

The subject of this submission is the addition of a Ø3.6mm version of the INnate screw to the system to be offered in lengths of 25 to 55mm.

INDICATIONS FOR USE

The ExsoMed INnate Cannulated 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.

TECHNOLOGICAL CHARACTERISTICS

The proposed modified device is substantially equivalent to the predicate, the ExsoMed ITN Cannulated Screw System. The design, materials, and intended use of the modified device are the same as the predicate devices. The mechanism of action of the 3.6mm INnate Cannulated Screw System is identical to the predicate devices in the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, performance specification or method of operation. Both the subject and predicate Cannulated Screw Systems are cleaned, packaged and sterilized using the same materials and processes. The ExsoMed 3.6mm INnate cannulated screw system differs from the predicate only in diameter, length and pitch.

PERFORMANCE TESTING

Verification analyses consisting of functionality testing were performed to demonstrate the equivalence of the new and predicate devices. Specifically, following tests were performed:

- Driving Torque testing
- Torque to failure testing

- Engineering Calculations for torsional strength, bending strength and pullout resistance

In addition, simulated use testing was performed to validate the modified device meets user needs.

The results from these evaluations demonstrated that the subject INnate 3.6mm Cannulated Screws perform as intended.

CONCLUSION

The information summarized in the Design Control Activities Summary demonstrates that the modified INnate Cannulated Screws met the predetermined acceptance criteria for verification activities identified.

There is no change to the fundamental scientific technology, indicated use or material type for the proposed line extension devices.

ExsoMed concludes that the line extension devices (3.6mm INnate Cannulated Screws) introduce no new issues of safety or effectiveness compared with the predicate device.