DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ExsoMed Holdings Company, LLC
Mr. Richard Kovach
President/CEO
7227 N. 16th Street, Suite 245
Phoenix, Arizona 85020

September 1, 2017

Re: K171558
Trade/Device Name: ExsoMed ITN 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: August 13, 2017
Received: August 16, 2017

Dear Mr. Kovach:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171558

Device Name
ExsoMed ITN Cannulated Screw System

Indications for Use *(Describe)*
The ExsoMed ITN 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

DEVICE NAME	EXSOMED™ ITN CANNULATED SCREW SYSTEM
OWNER/SUBMITTER INFORMATION	ExsoMed Holding Company, LLC 7227 N. 16th Street, Suite 245 Phoenix, Arizona 85020
DATE OF PREPARATION	May 25, 2017
CONTACT	Richard L. Kovach Chief Executive Officer Tel: (602) 466-3186 Email: rkovach@ExsoMed.com
DEVICE NAME AND CLASSIFICATION	Trade Name: ExsoMed ITN Cannulated Screw System Common Name: Screw, Fixation, Bone Classification: 21 CFR 888.3040, II Product Code: HWC
INTENDED USE	The ExsoMed ITN 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.
DEVICE DESCRIPTION	The ExsoMed ITN Cannulated Screw System is a stainless-steel bone screw system designed for bone fixation. The headless design of the screw allows for the screw to be countersunk below the surface of the bone. The screws are offered in one thread diameter (4.0mm distal / 4.5mm proximal) and lengths between 35 and 75mm. The screws are designed for permanent implantation. Screw implantation is facilitated by the use of three accessory devices provided in a separate procedure kit: • A K-wire to be used as a guide • A cannulated reamer to be used over the K-wire to

	prepare the medullary cavity • A cannulated hexalobe driver
PREDICATE DEVICE(S)	**Primary** **Predicate:** SYNTHES 3.0MM HEADLESS COMPRESSION SCREWS **Common Name:** Screw, Fixation, Bone **Manufacturer:** SYNTHES (USA) **K Number:** K050636 **Clearance Date:** 04/21/2005 **Secondary** **Predicate:** ASNIS III CANNULATED SCREW SYSTEM **Common Name:** Screw, Fixation, Bone **Manufacturer:** HOWMEDICA OSTEONICS CORP. **K Number:** K000080 **Clearance Date:** April 3, 2000 **Reference** **Predicate:** ExsoMed™ SMALL BONE SCREW SYSTEM **Common Name:** Screw, Fixation, Bone **Manufacturer:** ExsoMed Holding Company, LLC **K Number:** K171407 **Clearance Date:** August 18, 2017
PREDICATE DESCRIPTION FROM LABELING	The Synthes 3.0 mm Headless Compression Screws are cannulated and are self-drilling / self-tapping with a stardrive mechanism, and have a threaded head which can be countersunk into the bone. The screws are available in short and long thread lengths ranging from 10 mm to 40 mm. The screws are available in Stainless Steel and a Titanium Alloy. The Asnis Ill Cannulated Screw System consists of self-tapping cannulated screws and the corresponding washers. All devices in the system are provided sterile and non-sterile. The thread diameters are 4.0, 5.0. 6.5, and 8.0mm. They are either fully or partially threaded. All screws are Records processed under self-drilling and self-tapping. There are washers corresponding to the 4.0mm and the 5.0mm screws respectively and one washer fitting for both diameters, 6.5mm and 8.0mm.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS	The ExsoMed ITN Cannulated Screw System • Has the same intended use as the predicate devices. • Has the same indications for use as the predicate devices. • Is manufactured from the same materials as the predicate devices. • The range of sizes of the subject screws are is similar to the predicate devices. • Both the subject devices and the predicates are inserted into bone with the assistance of the driver bone fixation.
NON-CLINICAL PERFORMANCE TESTING	Bench testing studies were conducted to demonstrate the equivalence of the new and predicate devices. The following tests were conducted: • Torsional Properties Per ASTM F543-13 Annex 1 • Driving Torque Testing Per ASTM F543-13 Annex 2 • Pullout per ASTM F543-13 Annex 3 • Self-Tapping Performance per ASTM F543-13 Annex 4 (SpikeScrew only) • 4 point bending per ASTM F1264-14 • Pyrogenicity per Kinetic Chromogenic LAL Assay The results from these evaluations demonstrated that the subject screws performed comparably to the predicate device.
CONCLUSION	The subject, Exsomed ITN Cannulated Screw System, and the predicate device have the same technological characteristics, method of use, and materials. The performance testing completed and comparison of technological characteristics of the predicates and the subject device demonstrate the subject devices are substantially equivalent.