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 Holding Company, LLC
Richard L. Kovach
Chief Executive Officer
7227 N. 16th Street, Suite 245
Phoenix, Arizona 85020

August 18, 2017

Re: K171407
Trade/Device Name: ExsoMed ArcPhix and ExsoMed ArrowPhix
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 25, 2017
Received: July 25, 2017

Dear Richard 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 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171407

Device Name

ExsoMed ArcPhix and ExsoMed ArrowPhix

Indications for Use *(Describe)*

ExsoMed ArcPhix and ArrowPhix are indicated for use in the surgical fixation of small bones, bone fragments, and osteotomies. The devices are not indicated for soft tissue fixation.

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™ SMALL BONE SCREW SYSTEM
OWNER/SUBMITTER INFORMATION	ExsoMed Holding Company, LLC 7227 N. 16th Street, Suite 245 Phoenix, Arizona 85020
DATE OF PREPARATION	May 12, 2017
CONTACT	Richard L. Kovach Chief Executive Officer Tel: (602) 466-3186 Email: rkovach@ExsoMed.com
DEVICE NAME AND CLASSIFICATION	Trade Name: ExsoMed ArcPhix and ExsoMed ArrowPhix Common Name: Screw, Fixation, Bone Classification: 21 CFR 888.3040, II Product Code: HWC
INTENDED USE	The ArcPhix and ArrowPhix are intended for permanent fixation of small bones and small bone joints.
INDICATIONS FOR USE	ExsoMed ArcPhix and ArrowPhix are indicated for use in the surgical fixation of small bones, bone fragments, and osteotomies. The devices are not indicated for soft tissue fixation.
DEVICE DESCRIPTION	The Exsomed Small Screw system are stainless steel compression bone screws contained in sterile procedure kits. The ArcPhix screws are offered in two lengths, 28mm or 36mm by 3.2mm with an 18-degree bend. The ArrowPhix is a straight screw 26mm by 2.5mm. Implantation is facilitated by use of accessories provided in a sterile kit: • Implant • K-wire used as a guide

	• Drill to prepare the bones to receive the implant • Hexalobe driver for insertion of the bone screw
PREDICATE DEVICE(S)	**Primary Predicate:** **Name of Device:** SBI AutoFix system **Manufacturer:** Small Bone Innovations International S.A. **K Number:** K052576 **Approval Date:** 11/07/2005
PREDICATE PRINCIPALS OF OPERATION	Small bone screws, delivered in a sterile kit including implantation instrumentation
COMPARISON OF TECHNOLOGICAL CHARACTERISTICS	The ExsoMed Small Screws • have the same intended use as the predicate device. • are manufactured from the same materials as the predicate devices. • range of sizes of the subject screws are is similar to the predicate device. • Both the subject devices and the predicates are inserted into bone with the assistance of the driver for compression of the fracture and stabilization of the bone.
NON-CLINICAL PERFORMANCE TESTING	Bench testing studies were conducted to demonstrate the performance of the subject 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) Engineering analysis has been conducted demonstrating that the subject devices outperform the SBI Autofix screws in torsional and bending strength.

	Additionally, endotoxin testing has been completed on the subject device. The results from these evaluations demonstrated that the ArcPhix and ArrowPhix perform in a substantially equivalent manner to the predicate device.
CONCLUSION	The Exsomed Small Bone screws and the predicate devices have the same technological characteristics, method of use, and materials. The performance testing, engineering analysis and comparison of technological characteristics of the predicate and the subject devices demonstrate the subject devices are substantially equivalent.