February 13, 2023

Orthopaedic Implant Company
Douglas Fulton
Quality Assurance Manager
770 Smithridge Dr. #400
Reno, Nevada 89502

Re: K223761
Trade/Device Name: OIC Intramedullary 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: December 13, 2022
Received: December 15, 2022

Dear Douglas Fulton:

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 -S

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)*

K223761

Device Name

OIC Intramedullary Screw System

Indications for Use *(Describe)*

The OIC Intramedullary Screw System is indicated for the fixation of intra-articular and extra-articular fractures, mal-unions, non-unions or osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints. The device is intended for use in adults.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared 2/9/2023

Name and Address of Manufacturer:
The Orthopaedic Implant Company (OIC)
770 Smithridge Drive, Suite 400
Reno, NV 89502

Contact:
Douglas Fulton
Quality Assurance Manager
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Fax: 775-636-8284
Email: doug@orthoimplantcompany.com

Device Identification:
Trade Name: OIC Intramedullary Screw System
Common Name: Screw, Fixation, Bone
Regulation Name, Number: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR 888.3040
Classification: Class II
Panel: Orthopedic
Product Code: HWC

Indications for Use:
The OIC Intramedullary Screw System is indicated for the fixation of intra-articular and extra-articular fractures, mal-unions, non-unions or osteotomies of small bones and small bone fragments, as well as arthrodesis of small joints. The device is intended for use in adults.

Device Description:
The OIC Intramedullary Screw System consists of stainless steel screws and instruments to facilitate implantation. The screws come in two diameters, 3.6mm and 4.5mm, and range in length from 25mm to 80mm. The system also includes the instruments used to implant the screws.
The OIC Intramedullary Screw System is provided non-sterile and is steam-sterilized by the medical facility prior to implantation.

The screws are manufactured material that conforms to:
ASTM F138, Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

Comparison of Technological Characteristics (Substantial Equivalence):

The primary predicate device is:	Exsomed Corporation K183603 Innate Cannulated Screw System
Additional predicate devices:	Synthes USA K050636 Synthes 3.0mm Headless Compression Screws
	Orthopaedic Implant Company K113123 OIC Cannulated Screw System
	Orthopaedic Implant Company K181184 OIC Intramedullary Nail System

The OIC Intramedullary Screw System has the following similarities to those which previously received 510(k) concurrence:
· has the same indicated use,
· uses the same operating principle,
· incorporates a very similar design, and
· incorporates the same materials

Performance Testing:
Torsional, driving torque and axial pullout strength testing were performed on the OIC and Synthes screws per ASTM F543, “Standard Specification and Test Methods for Metallic Medical Bone Screw” annex A1, A2 and A3. The screws were found to have acceptable mechanical characteristics for the intended uses.

Conclusion:
The OIC Intramedullary Screw System described in this submission is substantially equivalent to the predicate devices.