June 11, 2024

OSTEONIC Co., Ltd.
Hye-Min Ahn
Assistant Manager
1206Ho, 38 Digital-ro 29-gil
Guro-gu, Seoul 08381
Korea, South

Re: K230546
Trade/Device Name: SIGNEX
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 11, 2024
Received: June 10, 2024

Dear Hye-Min Ahn:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tejen D. Soni -S

For
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)*
K230546

Device Name
SIGNEX

Indications for Use *(Describe)*
The SIGNEX plates and screws are indicated for the fixation of upper extremity (humerus, olecranon, radius, ulna, metacarpals, phalanges), lower extremity (femur, tibia, fibula, tarsals, metatarsals, phalanges), and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Hand System is indicated for fixation of hand (metacarpals, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Wrist System is indicated for fixation of wrist (distal radius, ulna) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Forearm System is indicated for fixation of forearm (radius and ulna) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Elbow System is indicated for fixation of elbow (distal humerus, olecranon, proximal radius and ulna) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Humerus System is indicated for fixation of humerus fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Foot System is indicated for fixation of foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Fibula System is indicated for fixation of fibula fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Tibia System is indicated for fixation of tibia fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Femur System is indicated for fixation of femur fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

The SIGNEX Clavicle System is indicated for fixation of clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

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

1. Date Prepared

June 10, 2024

2. Submitter

OSTEONIC Co., Ltd.
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3. Device

Trade Name: SIGNEX
Common Name: Plate, Fixation, Bone / Screw, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Regulatory Class: II
Product: HRS, HWC

4. Predicate Device

510(k) Number: K123241
Device Name: Arthrex Fracture Plates
Manufacturer: Arthrex Inc.

Reference Device
510(k) number: K141489
Device Name: LINOS MOH Hand Plating System
Manufacturer: KLS Martin L.P.

510(k) number: K092609
Device Name: Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP)
Manufacturer: SYNTHES (USA)

5. Device Description

The SIGNEX plates and screws are intended for closure /or bone fixation of fractures, fusion, osteotomies, non-union, malunion and reconstruction of hand, wrist, forearm, elbow, humerus, foot, fibula, tibia, femur and clavicle.

This is comprised of plates and screws. The plates are made of Pure Titanium (ASTM F67), Ti-6Al-4V ELI Titanium alloy (ASTM F136), and Screws are made of Ti-6Al-4V ELI Titanium alloy (ASTM F136). The plates and screws are single-use only, non-sterile products. so, those must be sterile before use.

6. Indications for Use

The SIGNEX plates and screws are indicated for the fixation of upper extremity (humerus, olecranon, radius, ulna, metacarpals, phalanges), lower extremity (femur, tibia, fibula, tarsals, metatarsals, phalanges), and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Hand System is indicated for fixation of hand (metacarpals, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Wrist System is indicated for fixation of wrist (distal radius, ulna) fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Forearm System is indicated for fixation of forearm (radius and ulna) fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Elbow System is indicated for fixation of elbow (distal humerus, olecranon, proximal radius and ulna) fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Humerus System is indicated for fixation of humerus fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Foot System is indicated for fixation of foot (tarsal, metatarsal, phalangeal) fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Fibula System is indicated for fixation of fibula fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Tibia System is indicated for fixation of tibia fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Femur System is indicated for fixation of femur fractures, fusions, osteotomies, non-unions, malunions and reconstructions. The SIGNEX Clavicle System is indicated for fixation of clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
The tests of SIGNEX included:
・Cytotoxicity (ISO 10993-5)
・Sensitization (ISO 10993-10)
・Irritation or Intracutaneous reactivity (ISO 10993-10)
・Systemic toxicity (ISO 10993-11)
・Genotoxicity (ISO 10993-3)
・Pyrogen testing (ISO 10993-6)
・Implantation testing (ISO 10993-11)

SIGNEX is considered tissue/bone contacting for a duration of longer than 30 days. SIGNEX's plate and screw materials conform to ASTM F67 and ASTM F136 respectively for chemical composition.

Mechanical testing
・Torsion test (ASTM F543)
・Axial pullout strength test (ASTM F543)
・Driving torque test (ASTM F543)
・4-Point bending test (ASTM F382)

The results of mechanical testing and theoretical analysis demonstrate SIGNEX to be substantially equivalent to the identified predicate device. The acceptance criteria for the mechanical testing were all met, supporting the overall conclusion of substantial equivalence for SIGNEX.

Clinical Studies
No clinical data were necessary for the demonstration of substantial equivalence.

8. Substantial Equivalence Comparison

Description	Subject Device	Predicate Device	Reference Device	Reference Device	Equivalence Discussion
Manufacturer	OSTEONIC Co., Ltd.	Arthrex Inc.	KLS Martin L.P.	SYNTHES (USA)	-
Product Name	SIGNEX	Arthrex Fracture Plate	LINOS MOH Hand Plating System	Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP)	-
510(k) No.	K230546	K123241	K141489	K092609	-
Product Code	HRS, HWC	HRS, HWC	HRS	HRS, HWC	Same
Regulatory Class	Class II	Class II	Class II	Class II	Same
Indications for Use	The SIGNEX plates and screws are indicated for the fixation of upper extremity (humerus, olecranon, radius, ulna, metacarpals, phalanges), lower extremity (femur, tibia, fibula, tarsals, metatarsals, phalanges), and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions. See Section 6 of this 510(k) Summary for the complete indications for use (IFU) statement.	The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula.	The LINOS MOH Hand Plating System is used for stabilization and fixation of fractures, revision procedures, -joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.	The Synthes 3.5mm Curved Narrow and Broad LCP Plates are intended for fixation of fractures, osteotomies and non-unions of clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia and fibula, particularly in osteopenic bone for adult patients. The Synthes 4.5mm Curved Narrow and Broad LCP Plates are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of periprosthetic fractures, osteopenic bone, and	Similar

Description	Subject Device	Predicate Device	Reference Device	Reference Device	Equivalence Discussion
				non-unions or malunions in adult patients. The 3.5mm and 4.5mm Curved Narrow and Broad LCP Plates are also indicated for fracture fixation of diaphyseal and metaphyseal areas of long bones in pediatric patients.	
Anatomical Sites	Hand, Wrist, Forearm, Elbow, Humerus, Foot, Fibula, Tibia, Femur, Clavicle	Ankle, Foot, Hand, Wrist, Clavicle, Scapula, Olecranon, Humerus, Radius, Ulna, Tibia Calcaneus, Fibula	Hand, Wrist, Fingers, Feet, Ankles, Toes	Clavicle, Scapula, Olecranon, Humerus, Radius, Pelvis, Distal tibia, Fibula	Same
Material	· Plate Pure Titanium (ASTM F67), Titanium alloy (ASTM F136) · Screw Titanium alloy (ASTM F136)	Titanium, Stainless steel	CP Titanium, Ti-6Al-4V Titanium Alloy	Titanium, Stainless steel	Similar
Surface Treatment	· Plate: Anodizing · Screw: Anodizing	· Plate: Anodizing · Screw: Anodizing	· Plate: Anodizing · Screw: Anodizing	· Plate: Anodizing · Screw: Anodizing	Similar
Structure	The plate is composed of various anatomical shapes such as straight, Y-, T-, square shapes, and so on. The screw is composed of cannulated and non-cannulated screws.	The plate is composed of various anatomical shapes such as straight, Y-, T-, square shapes, and so on. The screw is composed of cannulated and non-cannulated screws.	The plate is pre-curved to follow the natural curves of the hand and feet bones. The screw is composed of locking and non-locking screws.	The plate is composed of various anatomical shapes. The screw is composed of various length of locking screws.	Similar
Product Size	· Plate length (6.90 to 280.00 mm), thickness (0.60 to 5.00 mm)	· Plate length (50 to 244 mm) · Screw	· Plate thickness (0.6 to 3.0 mm) · Screw	· Plate length (28 to 479 mm) · Screw	Similar

Description	Subject Device	Predicate Device	Reference Device	Reference Device	Equivalence Discussion
	· Screw length (5.00 to 140.00 mm), diameter (1.30 to 5.00 mm)	diameter (2.5 to 6.7 mm)	length (2.0 to 32.0 mm), diameter (1.0 to 2.7 mm)	length (10 to 95 mm), diameter (3.5 to 5.0 mm)	Refer to Discussion below.
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same
Single Use/ Reuse	Single-use	Single-use	Single-use	Single-use	Same
Shelf-life	N/A	N/A	N/A	N/A	-

Discussion

Since there is the difference in size of plate and screw between the subject device and the predicate device, the reference devices were compared for supporting the difference of the subjective device.

Screw length was not within the range of predicate device and reference device. However, its safety and effectiveness were demonstrated as a result of performance tests according to FDA guidance and ASTM F543. Since they met the acceptance criteria of FDA guidance, and the comparison test result was equal to or greater than the predicate device (K092609), the difference of screw length is not a significant difference that raise questions of safety and effectiveness.

9. Conclusions

As a result of the substantial equivalence comparison, the subject device is substantially equivalent with the predicate device except for the product size. Therefore, the reference devices were added to support the difference of product size. In consequence, the product size of subject device is covered in the range of the predicate device and the reference devices, except of screw length. However, it has been demonstrated that difference in screw length does not raise questions of safety and effectiveness.

In conclusion, the subject device, SIGNEX, is determined to be substantially equivalent to the predicate device (K123241) and the reference devices (K141489, K092609).