May 29, 2025

OSTEONIC Co., Ltd.
℅ Sanglok Lee
Consultant
WISE COMPANY Inc.
#1108, 204 Gasan digital 1-ro, Geumcheon-gu
Seoul, 08502
Korea, South

Re: K243469
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: March 13, 2025
Received: March 14, 2025

Dear Sanglok Lee:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferriera, MS
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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K243469 |

Please provide the device trade name(s).

SIGNEX

Please provide your Indications for Use below.

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.The SIGNEX Universal Plates are indicated for fixation of arm (humerus, radius, ulna), leg (femur, tibia, fibula), and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# K243469

# 510(k) Summary

## 1. Date Prepared

May 8, 2025

## 2. Applicant

OSTEONIC Co., Ltd.
405Ho, 505-2Ho, 505-3Ho, 508Ho, 603Ho, 902Ho, 1004Ho, 1005Ho, 1201Ho, 1202Ho, 1206Ho, 38, Digital-ro 29-gil, Guro-gu, 102Ho, 103Ho, 24, Digital-ro 27-gil, Guro-gu, 1012Ho, 1013Ho, 272, Digital-ro, Guro-gu, Seoul, Korea
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## 3. Submission Correspondent

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Contact Person: Sanglok, Lee
E-mail: info@wisecompany.org

## 4. Subject 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 Code: HRS, HWC

## 5. Primary Predicate Device

510(k) Number: K230546
Device Name: SIGNEX
Manufacturer: OSTEONIC Co., Ltd.

## 6. Additional Predicate Device

- Acumed Congruent Bone Plate System (K102998)
- APTUS 1.5 TriLock (K102537)
- APTUS 2.0 RADIAL HEAD SYSTEM (K090053)
- APTUS FOOT 3.5 SYSTEM (K110908)
- APTUS FOOT SYSTEM (K091479)
- APTUS TITANIUM OSTEOSYNTHESIS SYSTEM (K051567)
- APTUS ULNA PLATES (K103332)
- DEPUY SYNTHES TOMOFIX OSTEOTOMY SYSTEM (K141796)
- SMALL FRAGMENT DYNAMIC COMPRESSION LOCKING (DCL) SYSTEM (K000684)
- SYNTHES (USA) 2.4 MM VA-LCP TWO COLUMN VOLAR DISTAL RADIUS PLATES (K083694)
- SYNTHES (USA) 3.5/4.5MM LCP MEDIAL PROXIMAL TIBIA PLATES (K050646)
- SYNTHES (USA) 3.5MM LCP HOOK PLATE (K082072)
- SYNTHES (USA) CLAVICLE HOOK PLATES (K061753)
- SYNTHES (USA) LCP PROXIMAL HUMERUS PLATES, LONG (K041860)
- SYNTHES 2.7 MM/3.5 MM LCP DISTAL FIBULA PLATES (K083213)

- SYNTHES 3.5 MM AND 4.55 MM CURVED NARROW AND BROAD LOCKING COMPRESSION PLATES (LCP) (K092609)
- SYNTHES 3.5MM LCP CLAVICLE PLATE SYSTEM (K111540)
- SYNTHES CORTICAL SCREWS (K112583)
- SYNTHES LCP DISTAL FEMUR PLATES (K062564)
- SYNTHES LOCKING DISTAL RADIUS PLATING SYSTEM (K012114)
- SYNTHES VARIABLE ANGLE LCP ELBOW SYSTEM (K120070)
- SYNTHS ONE-THIRD TUBULAR DCL PLATE (K011335)

**7. Device Description**

This product is 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) or 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.

**8. 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. The SIGNEX Universal Plates are indicated for fixation of arm (humerus, radius, ulna), leg (femur, tibia, fibula), and clavicle fractures, fusions, osteotomies, non-unions, malunions and reconstructions.

**9. Performance Data**

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate. The test results demonstrated that the subject device complies with the following standards:

**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 materials conform to ASTM F67 or 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 primary predicate device and additional predicate devices (multiple Acumed, Medartis, and Synthes devices used for side-by-side testing). 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.

## 10. Substantial Equivalence Comparison

| Description | Subject Device | Primary Predicate Device | Additional Predicate Device | Equivalence Discussion |
|---|---|---|---|---|
| Manufacturer | OSTEONIC Co., Ltd. | OSTEONIC Co., Ltd. | SYNTHES (USA) | - |
| Product Name | SIGNEX | SIGNEX | Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) | - |
| 510(k) No. | K243469 | K230546 | K092609 | - |
| Product Code | HRS, HWC | HRS, HWC | HRS, HWC | Same |
| Regulatory Class | 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.<br><br>See Section 6 of this 510(k) Summary for the complete indications for use (IFU) statement. | 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.<br><br>See Section 6 of this 510(k) Summary for the complete indications for use (IFU) statement. | 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.<br><br>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 non-unions or | Same |

| Description | Subject Device | Primary Predicate Device | Additional Predicate Device | Equivalence Discussion |
|---|---|---|---|---|
| | | | malunions in adult patients.<br>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 | Hand, Wrist, Forearm, Elbow, Humerus, Foot, Fibula, Tibia, Femur, Clavicle | Clavicle, Scapula, Olecranon, Humerus, Radius, Pelvis, Distal tibia, Fibula | Same |
| Material | · Plate<br>Pure Titanium (ASTM F67), Titanium alloy (ASTM F136)<br>· Screw<br>Titanium alloy (ASTM F136) | · Plate<br>Pure Titanium (ASTM F67), Titanium alloy (ASTM F136)<br>· Screw<br>Titanium alloy (ASTM F136) | · Titanium, Stainless steel | Same |
| Surface Treatment | · Plate: Anodizing, non-anodizing<br>· Screw: Anodizing, non-anodizing | · Plate: Anodizing<br>· Screw: Anodizing | · Plate: Anodizing<br>· Screw: Anodizing | Equivalent |
| Structure | The plate is composed of various anatomical shapes such as straight, Y-, T-, square shapes, and so on.<br>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.<br>The screw is composed of cannulated and non-cannulated screws. | The plate is composed of various anatomical shapes.<br>The screw is composed of various length of locking screws. | Same |
| Product Size | · Plate<br>length (6.9 to 438.0 mm), thickness (0.6 to 6.0 mm)<br>· Screw<br>length (10.0 to 90.0 mm), diameter (2.4 to 5.0 mm) | · Plate<br>length (8.6 to 280.0 mm), thickness (0.8 to 5.0 mm)<br>· Screw<br>length (5.0 to 140.0 mm), diameter (1.3 to 5.0 mm) | · Plate<br>length (28 to 479 mm)<br>· Screw<br>length (10 to 95 mm), diameter (3.5 to 5.0 mm) | Refer to Discussion 1. Below. |
| Sterilization | Non-sterile | Non-sterile | Non-sterile | Same |
| Single Use/ Reuse | Single-use | Single-use | Single-use | Same |
| Shelf-life | N/A | N/A | N/A | Same |

**Discussion 1.**

Since there is the difference in size of plates and screws between the subject device and the primary predicate device, the additional predicate was compared for supporting the difference of the subjective device.

The plates of the subject device have a slight difference in product size from primary predicate device(K230546) and additional predicate devices. However, as a result of comparative testing with legally marketed device, the safety and effectiveness of the plate of the subject device were demonstrated. Therefore, the difference of plate size is not a significant difference that raise questions of safety and effectiveness.

## 11. Conclusions

As a result of the substantial equivalence comparison, the subject device is substantially equivalent with the primary predicate device except for the product size. Therefore, the additional predicate was added to support the difference of product size. However, since there is a slight difference that is not covered by primary predicate device and additional predicate, the safety and the effectiveness of the subject device were confirmed through the comparative test with the legally marketed devices.

In conclusion, the subject device is determined to be substantially equivalent to the primary predicate device (K230546) and the additional predicate devices (many).