October 27, 2022

Hospital Equipment Manufacturing Company
Himanshu Sachdeva
Director
A19/A20, Sector 7
Noida, Uttar Pradesh 201301
India

Re: K222282
Trade/Device Name: HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, HEMC BRAND of DHS Plating System
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: July 29, 2022
Received: July 29, 2022

Dear Himanshu Sachdeva:

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, MPH
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222282

Device Name
HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System

Indications for Use *(Describe)*
The 2.4mm Secure Locking Variable Angle Distal Radius Plate and Ø2.4 mm Secure Locking Screws, Self-Tapping are intended for fixation of complex intra- and extra-articular fractures arid osteotomies of the distal radius.

The 2.7mm/3.5mm Secure Locking Distal Humerus Medial Plate, 2.7mm/3.5mm Secure Locking Distal Humerus, Dorsolateral Plate, and 2.7mm/3.5mm Secure Locking Distal Humerus Plate, Dorsolateral With Lateral Support are indicated for intra-articular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

The 3.5mm Secure Locking Small Plate, 3.5mm Secure Locking T-Plate, Small with 3 Head Holes, and Ø3.5 mm Secure Locking Screws, Self-Tapping, are indicated for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula.

The 3.5 mm Secure Locking Superior-Anterior Clavicle Plate and 3.5 mm Secure Locking Superior-Anterior Clavicle Plate With Lateral Extension is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

The 3.5mm Secure Locking Olecranon Plate is indicated for fractures, osteotomies, malunions and non-unions of the olecranon.

The 3.5 mm Secure Locking Philos Proximal Humeral Internal Plate is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

The 4.5/5.0mm Secure Locking Narrow LC Dynamic Compression Plate is indicated for fixation of various long bones, such as the humerus, femur and tibia and for use in fixation of peri-prosthetic fractures, and fixation of nonunions or malunions in adult patients.

The 4.5mm/5.0mm Secure Locking Distal Femoral Plate is intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures, nonunions and malunions, and osteotomies of the femur.

The 4.5mm/5.0mm Secure Locking Medial Proximal Tibia Plate is intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. Also, for use in the fixation of nonunions and malunions of the medial proximal tibia and tibia shaft.

The 4.5mm/5.0mm Secure Locking L Buttress Plate and 4.5mm/5.0mm Secure Locking T Buttress Plate are intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia. Also, for use in fixation of non-unions and malunions.

The 3.5mm/4.5mm/5.0mm Secure Locking Distal Tibia Plates are intended treatment of non-unions, malunions, and fractures of the distal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar,

combinations of lateral wedge and depression, and fractures with associated shaft fractures.

The Ø3.5mm CORTICAL SCREW and Ø4.5mm CORTICAL SCREW are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The Ø2.7 mm Secure Locking Screws, Self Tapping, and Ø 2.7mm Cortical Screws are intended for fractures and osteotomies of small bones and bone fragments, including the foot, ankle, and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The Ø5.0mm Secure Locking Screws, Self-Tapping are intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of non-unions or malunions.

The 6.5mm Cancellous Screw, 16mm Thread, 32 Thread, Full Thread, Ø4.0mm CANCELLOUS SCREW, Partial Thread, Full Thread, and Ø4.0mm SMALL CANCELLOUS CANNULATED SCREW, Partial Thread, Full Thread are indicated for use in hindfoot and midfoot fusions, subtalar fusions, calcaneal osteotomies, midfoot reconstruction, and ankle arthrodeses.

The 6.5mm Cancellous Cannulated Screw, 16mm Thread, 32 Thread, Full Thread, and 7.0mm Cancellous Cannulated Screw, 16mm Thread, 32 Thread, Full Thread, are indicated for fracture fixation of large bones and large bone fragments, such as tibial plateau fractures, ankle arthrodeses, intercondylar femur fractures; and subtalar arthrodeses.

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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K222282 – 510(k) Summary

Pre-market Notification 510(k)Summary as required by Section 807.92

General Company Information as required by 807:92(a)

a(1). The submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

510(k) submitter	**:**	Hospital Equipment Mfg. Co.
Head office Address	**:**	D-313, D Block, Sector 63, Noida, Uttar Pradesh- 201301, India
Manufacturing Unit Address	**:**	A-19/ A-20, Sector-7, Noida, District Gautam Budha Nagar, UP-201301
Contact person name	**:**	Mr. Himanshu Sachdeva
Title	**:**	Director
Phone number	**:**	+91 9810053889
Dated	**:**	October 25, 2022

This is a bundled submission.

Throughout the submission there is a mention of **HEMC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, that represents the range of products covered under this 510(k) submission.

a(2). The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Proprietary Name: HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System

Common or Usual Name:
- Orthopedic Bone Plates
- Orthopedic Bone Screws

Classification Name:
- PLATES, FIXATION, BONE
- SCREWS, FIXATION, BONE

Product Code: HRS, HWC
Device Class: Class II
Review Panel: Orthopedic

Regulation Number: 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories and 21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener

HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are further sub divided into following categories:

S. No.	Type
01	Mini Fragment, Small Fragment and Large Fragment
02	Corresponding Bone Screws - Locking and Non-Locking Version

Generally, the bone plates are used with cortical (cortex), cancellous, and locking and non-locking screws. These bone plates are generally designed on the basis of the bone contour and anatomy.

a(3). Identification of the Predicate Devices:

The following are a list of the 510(k) predicate devices with which we are declaring substantial equivalence:

No.	Primary Predicate Device
1	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
No.	**Other Predicate Devices**
2	Synthes 3.5mm LCP Clavicle Plate System (K111540)
3	Synthes Variable Angle LCP Elbow System (K120070)
4	Synthes Variable Angle Locking Compression Plates Distal Radius System (K071184)
5	Synthes 3.5mm LCP Distal Humerus System (K033995)
6	Synthes (USA) 3.5 / 4.5mm LCP® Medial Proximal Tibia Plate (K032269)
7	Synthes (USA) LCP® Proximal Humerus Plates, Long (K041860)
8	Synthes LCP Distal Femur Plates (K062564)
9	Synthes (USA) Medial Distal Tibia Plate (K001945)
10	Synthes LCP Proximal Tibia Plate (K011978)
11	Synthes Cortical Screws (K112583)
12	Synthes (USA) 6.5 mm Cancellous Screws (K061621)
13	Synthes 6.5mm Cannulated Screws (K021932)
14	Synthes 7.0/7.3 cannulated cancellous screws (K962011)

a(4). A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device:

Device Description:
HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System consists of various shapes and sizes of plates featuring compression and locking holes, full-threaded-cortical, locking self-tapping screws, compression and dynamic screws. The subject device system also consists of a variety of general use instruments (Class I), which include drill bits, forceps, plate benders, and drill guides.

The plates and screws are manufactured from Stainless Steel and Titanium alloy.

The system contains several models based on the size of the device and application site such as fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, ankle, or other bones appropriate for the size of the device. The plate implants are in many models available, such as:, Reconstruction Plates, T-Plates, Anatomical Plates, Clavicle Plates.

These all are mainly divided into:

- Large Fragment Plates
- Small Fragment Plates
- Mini Fragment Plates

The locking screw implants are offered in corresponding diameter ranges from 2.4mm, 2.7mm, 3.5mm, 5.0mm diameters with lengths varying from a minimum length of 6 mm to maximum length of 90mm.

The non-locking screw implants are offered in 2.7mm, 3.5mm and 4.5mm diameters, with lengths ranging from 10mm to 80mm.

The cancellous screw implants are 4.0mm and 6.5mm in diameter, with lengths ranging from 10 to 120 mm. The cancellous cannulated screw implants are offered in 4.0mm, 6.5mm and 7.0mm diameters and lengths ranging from 16mm to 130 mm.

HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are provided non-sterile, the products must be sterilized prior to use. All implants are for single use only.

a(5). A statement of the intended use of the device.

HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are indicated for treating fractures of various bones including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula),and small bone (metacarpals, metatarsals, phalanges).

Indications for Use:

The ***2.4mm Secure Locking Variable Angle Distal Radius Plate*** and ***Ø2.4 mm Secure Locking Screws, Self-Tapping*** are intended for fixation of complex intra- and extra-articular fractures arid osteotomies of the distal radius.

The ***2.7mm/3.5mm Secure Locking Distal Humerus Medial Plate***, ***2.7mm/3.5mm Secure Locking Distal Humerus, Dorsolateral Plate***, and ***2.7mm/3.5mm Secure Locking Distal Humerus Plate, Dorsolateral With Lateral Support*** are indicated for intra-articular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

The ***3.5mm Secure Locking Small Plate***, ***3.5mm Secure Locking T-Plate, Small with 3 Head Holes***, and ***Ø3.5 mm Secure Locking Screws, Self-Tapping***, are indicated for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula.

The ***3.5 mm Secure Locking Superior-Anterior Clavicle Plate*** and ***3.5 mm Secure Locking Superior-Anterior Clavicle Plate With Lateral Extension*** is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

The ***3.5mm Secure Locking Olecranon Plate*** is indicated for fractures, osteotomies, malunions and non-unions of the olecranon.

The ***3.5 mm Secure Locking Philos Proximal Humeral Internal Plate*** is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

The ***4.5/5.0mm Secure Locking Narrow LC Dynamic Compression Plate*** is indicated for fixation of various long bones, such as the humerus, femur and tibia and for use in fixation of peri-prosthetic fractures, and fixation of nonunions or malunions in adult patients.

The ***4.5mm/5.0mm Secure Locking Distal Femoral Plate*** is intended for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures, nonunions and malunions, and osteotomies of the femur.

The ***4.5mm/5.0mm Secure Locking Medial Proximal Tibia Plate*** is intended to buttress metaphyseal fractures of the medial tibia plateau, split-type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. Also, for use in the fixation of nonunions and malunions of the medial proximal tibia and tibia shaft.

The ***4.5mm/5.0mm Secure Locking L Buttress Plate and 4.5mm/5.0mm Secure Locking T Buttress Plate*** are intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia. Also, for use in fixation of non-unions and malunions.

The ***3.5mm/4.5mm/5.0mm Secure Locking Distal Tibia Plates*** are intended treatment of non-unions, malunions, and fractures of the distal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

The ***Ø3.5mm CORTICAL SCREW and Ø4.5mm CORTICAL SCREW*** are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneous, femur and fibula in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The ***Ø2.7 mm Secure Locking Screws, Self-Tapping***, and ***Ø 2.7mm Cortical Screws*** are intended for fractures and osteotomies of small bones and bone fragments, including the foot, ankle, and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The ***Ø5.0mm Secure Locking Screws, Self-Tapping*** are intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of non-unions or malunions.

The ***6.5mm Cancellous Screw, 16mm Thread, 32 Thread, Full Thread***, ***Ø4.0mm CANCELLOUS SCREW, Partial Thread, Full Thread***, and ***Ø4.0mm SMALL CANCELLOUS CANNULATED SCREW, Partial Thread, Full Thread*** are indicated for use in hindfoot and midfoot fusions, subtalar fusions, calcaneal osteotomies, midfoot reconstruction, and ankle arthrodeses.

The ***6.5mm Cancellous Cannulated Screw, 16mm Thread, 32 Thread, Full Thread***, and ***7.0mm Cancellous Cannulated Screw, 16mm Thread, 32 Thread, Full Thread***, are indicated for fracture fixation of large bones and large bone fragments, such as tibial plateau fractures, ankle arthrodeses, intercondylar femur fractures; and subtalar arthrodeses.

a(6). Summary of Technological Characteristics as compared to the predicate devices:

Substantial equivalence including comparison with predicate devices

A comparison between the **HEMC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

Following is the summary of parameters in which the comparison has been verified:

S.No.	Characteristics	Predicate Device Versus New Device (HEMC Brand)	Remarks
01	Indications for use	Similar intended use in New Device and Predicate device	Equivalent
02	Material	Same material used in New Device and Predicate device	Equivalent
03	Performance Standards	Same performance standards used in both New Device as well as predicate device	Equivalent
04	Sterilization	Same method of sterilization used in both New Device as well as Predicate device	Equivalent
05	Dimensional Verification	Same dimensions found in both New Device as well as Predicate device	Equivalent

b(1). Discussion on the non-clinical testing performed:

Following are the applicable product standards considered for non-clinical standards:
A:Material Standards
B: Performance Standards

A: Material Standards:

The material standards are the essential part to be complied to first, as it is the basis of manufacturing metallic surgical implants.

We have complied to following material standards:

1. ASTM F136: Standard specification for wrought Titanium-6 Aluminium-4 Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.
2. ASTM F138: Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum

stainless steel bar and wire for surgical implants.
3. ASTM F139: Standard Specification for Wrought 18Chromium-14Nickel-2.5MolybdenumStainlessSteel Sheet and Strip for surgical Implants

We have verified the purchased material compliance to these standards and copies of the relevant test results were provided in the submission.

B: Performance Standards:

The device performance of **HEMC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System has been demonstrated against the following applicable standards and FDA guidance documents to demonstrate substantial equivalence to the predicate devices:

- ASTM F382: Standard Specification and Test Method for Metallic Bone Plates ,
- ASTM F384: Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
- ASTM F543: Standard Specification and Test Methods for Metallic Medical Bone Screws.
- FDA guidance document, *"Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway" (December 2020)*
- FDA guidance document, *"Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway " (April 2022)*

For Bone Plates:
As per ASTM F382 and ASTM F384:
Static Four Point Bend Test: Conforms,
Dynamic Four Point Bend Test: Conforms

For Bone Screws:
As per ASTMF 543:
Torsional Properties: Conforms,
Driving Torque: Conforms,
Pull-out Test: Conforms

b(2). Discussion on the clinical evaluation referenced and relied upon:

HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are of similar design and pattern as well as similar intended use. Clinical information was not necessary to demonstrate substantial equivalence.

CONCLUSION:

General, Safety and Performance conclusion:
From the data available we can justify that the **HEMC BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in Section a(3). of this 510(k) summary.

Hence, these devices can be considered substantially equivalent to the predicate devices.