March 8, 2018

Meril Healthcare Pvt. Ltd.
% Meredith May
VP
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K171320
Trade/Device Name:
ARMAR™ / ARTIS™ Small Fragment and Calcaneal Plates & MBOSS™ / FIXION™ Screws
ARMAR™ / ARTIS™ Humerus and Olecranon Plates & MBOSS™/FIXION™ Screws
ARMAR™ / ARTIS™ Tibia and Buttress Plates & MBOSS™/FIXION™ Screws
ARMAR™ / ARTIS™ 2.4mm Plates & MBOSS™/FIXION™ Screws
ARMAR™ / ARTIS™ Clavical Hook Plate & MBOSS™/FIXION™ Screws
ARMAR™ / ARTIS™ Metaphyseal Plate & MBOSS™/FIXION™ Screws
ARMAR™ / ARTIS™ Calcaneal Plate & MBOSS™/FIXION™ Screws
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: January 30, 2018
Received: January 31, 2018

Dear Ms. May:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K171320

Device Name
ARMAR™ / ARTIS™ Small Fragment and Calcaneal Plates & MBOSS™/FIXION™ Screws

Indications for Use *(Describe)*

ARMAR™ / ARTIS™ Small Fragment and Calcaneal Plates & MBOSS™/FIXION™ Screws are indicated for temporary internal fixation and stabilization of osteotomies and fractures, such as:

- comminuted fractures
- supracondylar fractures
- extra-articular fractures
- fractures in osteopenic bone
- nonunions
- malunions

Smaller-sized ARMAR™ / ARTIS™ plates are used for small bones and small fragments of the hands and feet.

ARMAR™ / ARTIS™ Calcaneal plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures of the calcaneous.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K171320

Device Name
ARMAR™ / ARTIS™ Humerus and Olecranon Plate & MBOSS™/FIXION™ Screws

Indications for Use *(Describe)*

ARMAR™ / ARTIS™ Humerus and Olecranon plates & MBOSS™/FIXION™ Screws are intended for fractures and fracture dislocations, osteotomnies, and non-unions of the distal and proximal humerus, olecranon, and ulna in adult, particularly in osteopenic bone.

Specifically, distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distalhumerus. Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K171320

Device Name
ARMAR™ / ARTIS™ Tibia and Buttress Plates & MBOSS™/FIXION™ Screws

Indications for Use *(Describe)*

ARMAR™ / ARTIS™ Tibia and Buttress Plates & MBOSS™/FIXION™ Screws are intended for fixation of the ankle in adults. Specifically,

- Anterolateral Distal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia.
- Medial Distal and Proximal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
- L Buttress and T Buttress Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
- Proximal Lateral Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia, a Distal Tibia T Plates and Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K171320

Device Name
ARMAR™ / ARTIS™ 2.4mm Plates & MBOSS™/FIXION™ Screws

Indications for Use *(Describe)*

ARMAR™ / ARTIS™ 2.4mm Plates & MBOSS™/FIXION™ Screws are intended for Fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones 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)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K171320

Device Name
ARMAR™ / ARTIS™ Clavical Hook Plate & MBOSS™/FIXION™ Screws

Indications for Use *(Describe)*

ARMAR™ / ARTIS™ Clavical Hook Plate & MBOSS™/FIXION™ Screws is intended for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K171320

Device Name
ARMAR™ / ARTIS™ Metaphyseal Plate & MBOSS™/FIXION™ Screws

Indications for Use *(Describe)*

ARMAR™ / ARTIS™ Metaphyseal Plate & MBOSS™/FIXION™ Screws indicated for fractures, osteotomies, and non-unions of the radius and other small bones. Additionally, the Metaphyseal Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 *See PRA Statement on last page.*

510(k) Number *(if known)*
K171320

Device Name
ARMAR™ / ARTIS™ Calcaneal Plate & MBOSS™/FIXION™ Screws

Indications for Use *(Describe)*

ARMAR™ / ARTIS™ Calcaneal Plate & MBOSS™/FIXION™ Screws is intended for fixation of complex extra-articular and intra-articular fractures and osteotomies of the calcaneus.

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)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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PRAStaff@fda.hhs.gov
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Submitter's Name	Meril Healthcare Pvt. Ltd.
Submitter's Address	First Floor, H1-H3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191 Gujarat, India
Submitter's Telephone	352-377-1140
Submitter Contact	Umesh Sharma umesh.sharma@merillife.com
Contact Person	Meredith May 719-337-7579 VP, Empirical Consulting
Date Summary was Prepared	24th July 2017
Trade or Proprietary Name	ARMAR™ / ARTIS™ Small Fragment and Calcaneal Plates & MBOSS™ / FIXION™ Screws ARMAR™ / ARTIS™ Humerus and Olecranon Plates & MBOSS™/FIXION™ Screws ARMAR™ / ARTIS™ Tibia and Buttress Plates & MBOSS™/FIXION™ Screws ARMAR™ / ARTIS™ 2.4mm Plates & MBOSS™/FIXION™ Screws ARMAR™ / ARTIS™ Clavical Hook Plate & MBOSS™/FIXION™ Screws ARMAR™ / ARTIS™ Metaphyseal Plate & MBOSS™/FIXION™ Screws ARMAR™ / ARTIS™ Calcaneal Plate & MBOSS™/FIXION™ Screws
Common or Usual Name	Plate, Fixation, Bone Screw, Fixation, Bone
Classification	Class II per 21 CFR §888.3030 Class II per 21 CFR §888.3040
Product Code	HRS, HWC
Classification Panel	Division of Orthopedic Devices

I. DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Meril Healthcare Trauma System utilizes screws and plates of various lengths and designs to accommodate a variety of patient anatomies. The Trauma System utilizes medical grade stainless steel and titanium. Trauma System implant are provided clean and non-sterile with instructions for steam sterilization. The instruments are provided non-sterile and are reusable. The implants are provided non-sterile and are single use only.

II. INDICATIONS FOR USE

1. ARMAR™ / ARTIS™ Small Fragment and Calcaneal Plates & MBOSS™ / FIXION™ Screws

ARMAR™ / ARTIS™ Small Fragment and Calcaneal Plates & MBOSS™/FIXION™ Screws are indicated for temporary internal fixation and stabilization of osteotomies and fractures, such as:

- comminuted fractures
- supracondylar fractures
- extra-articular fractures
- fractures in osteopenic bone
- nonunions
- malunions

Smaller-sized ARMAR™ / ARTIS™ plates are used for small bones and small fragments of the hands and feet.

ARMAR™ / ARTIS™ Calcaneal plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures of the calcaneous.

2. ARMAR™ / ARTIS™ Humerus and Olecranon Plates & MBOSS™/FIXION™ Screws

ARMAR™ / ARTIS™ Humerus and Olecranon plates & MBOSS™/FIXION™ Screws are intended for fractures and fracture dislocations, osteotomnies, and non-unions of the distal and proximal humerus, olecranon, and ulna in adult, particularly in osteopenic bone.

Specifically, distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distalhumerus. Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

3. ARMAR™ / ARTIS™ Tibia and Buttress Plates & MBOSS™/FIXION™ Screws

ARMAR™ / ARTIS™ Tibia and Buttress Plates & MBOSS™/FIXION™ Screws are intended for fixation of the ankle in adults. Specifically,

- Anterolateral Distal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia.
- Medial Distal and Proximal Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,
- L Buttress and T Buttress Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia, and
- Proximal Lateral Tibia Plates are intended for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia, a Distal Tibia T Plates and

Distal Tibia L Plates are intended to buttress partial articular fractures and bone fragments of the distal tibia.

4. **ARMAR™ / ARTIS™ 2.4mm Plates & MBOSS™/FIXION™ Screws**
   ARMAR™ / ARTIS™ 2.4mm Plates & MBOSS™/FIXION™ Screws are intended for Fixation of complex intra- and extra-articular fractures and osteotomnies of the distal radius and other small bones in adults.

5. **ARMAR™ / ARTIS™ Clavical Hook Plate & MBOSS™/FIXION™ Screws**
   ARMAR™ / ARTIS™ Clavical Hook Plate & MBOSS™/FIXION™ Screws is intended for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

6. **ARMAR™ / ARTIS™ Metaphyseal Plate & MBOSS™/FIXION™ Screws**
   ARMAR™ / ARTIS™ Metaphyseal Plate & MBOSS™/FIXION™ Screws indicated for fractures, osteotomies, and non-unions of the radius and other small bones. Additionally, the Metaphyseal Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula.

7. **ARMAR™ / ARTIS™ Calcaneal Plate & MBOSS™/FIXION™ Screws**
   ARMAR™ / ARTIS™ Calcaneal Plate & MBOSS™/FIXION™ Screws is intended for fixation of complex extra-articular and intra-articular fractures and osteotomies of the calcaneus.

III. TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are similar between the subject and predicates:

- Indications for use
- Materials of manufacture
- Structural support mechanism
- Principle of operation
- Sizes

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K143331, K083654	Bone Plates	Zimmer	Primary
K121672, K120717, K082625	Plate System	Synthes	Additional
K121601, K120854	Ankle Trauma System	Synthes	Additional
K110125, K102694, K953644	Distal Radius System	Synthes	Additional
K061753	Clavicle Hook Plate	Synthes	Additional

K070946, K031573	Pelvic Plates	Synthes	Additional
K020401	Calcaneal Plate	Synthes	Additional
K112583, K000682	Cortical Screws and DCL System	Synthes	Additional
K071264, K102694, K092609, K000682	Foot and Ankle Plates	Synthes	Additional
K092609, K021932	Cancellous Screws	Synthes	Additional

IV. PERFORMANCE DATA

ARMAR™ / ARTIS™ plates and MBOSS™/FIXION™ screws have been tested in the following test modes:

- Static Four-point Bending per ASTM F382-99 (2008)
- Dynamic Four-point Bending per ASTM F382-99 (2008)
- Static Torsion per ASTM F543-13
- Static Axial Pullout per ASTM F543-13

The results of this non-clinical testing show that the strength of the ARMAR™ / ARTIS™ plates and MBOSS™/FIXION™ screws are sufficient for their intended use and substantially equivalent to legally marketed predicate devices.

V. CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the ARMAR™ / ARTIS™ plates and MBOSS™/FIXION™ screws are substantially equivalent to the predicate devices.