Meril Healthcare Pvt. Ltd.
Gayathri Nair
Senior Manager - Regulatory Affairs/Quality Assurance
Survey No. 135/2/B & 174/2,
First Floor, H1-H3, Meril Park,
Muktanand Marg, Chala,
Vapi - 396 191, Gujarat, INDIA

July 18, 2019

Re: K183532
Trade/Device Name: Latitud™ Hip Replacement System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: June 21, 2019
Received: June 25, 2019

Dear Gayathri Nair:

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,

FOR CAPT Raquel Peat, PhD, MPH, USPHS
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183532

Device Name
Latitud™ Hip Replacement System

Indications for Use *(Describe)*
The Latitud™ Hip Replacement System is intended for use in total hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is an evidence of sufficient sound bone to fix and support the components.

Total hip replacement is indicated for the following conditions:
• Non-inflammatory degenerative joint diseases including osteoarthritis, post-traumatic arthritis and avascular necrosis.
• Rheumatoid arthritis.
• Congenital hip dysplasia.
• Acute traumatic fracture of the femoral head or neck.
• Certain cases of Ankylosis.
• Dislocation of the hip.
• Correction of functional deformity.
• Revision of failed joint reconstruction or treatment.
• Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur.

Note:
• The Titanium coated Modular Acetabular Shell is intended for press-fit, uncemented use only.
• The Hydroxyapatite coated Uncemented Femoral Stem is intended for press-fit, uncemented use only.
• The Proximally coated Uncemented femoral stem is intended for press-fit, uncemented use only.
• The Cemented Femoral stem is intended for cemented use only.
• The Modular Acetabular Liner is intended for use with Modular Acetabular Shell.
• The CoCr Modular Femoral Head is intended to articulate with Modular Acetabular Liner to mate with uncemented stem or cemented stem.
• The Biolox® delta Modular Femoral Head is intended to articulate with Modular Acetabular Liner and to mate with uncemented stem or cemented stem.
• The Bone Screw and Apical Hole Occluder are intended for use with Modular Acetabular shell.
• The Centralizer and Cement Restrictor are intended for use with cemented stem only.

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.

Meril

5. 510(k) SUMMARY

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 92.

5.1 Applicant:

Meril Healthcare Private Limited
Survey No. 135/2/B & 174/2,
First Floor, H1-H3, Meril Park,
Muktanand Marg, Chala,
Vapi - 396 191, Gujarat, INDIA

5.2 Contact Person:

Gayathri Nair
Senior Manager- Regulatory Affairs/ Quality Assurance
Meril Healthcare Private Limited
E mail: Gayathri.Nair@merillife.com
Cell: +91 9909033393

5.3 Date prepared: July16, 2019

5.4 Device information:

Proprietary Name:	Latitud™ Hip Replacement System
Common / Usual Name:	Hip Joint Prosthesis
Classification name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
Product Code:	LZO
Device Class:	Class II

Meril

5.5 Predicate Devices

Latitud™ Hip Replacement System is utilizing the following devices to demonstrate substantial equivalence. Libertas – Hip Replacement System (K180973) is considered as the primary predicate (same Indications for use) and all other devices are included for performance comparison.

Manufacturer	Device Trade name	510(k) #
Maxx Orthopedics Inc, USA	Libertas – Hip Replacement System	K180973
Corin, USA	Trinity Acetabular cup System	K110087
DePuy Orthopaedics, Inc., USA	Marathon Acetabular Liner	K033273
Ortho Development Corporation, USA	Escalade Acetabular Cup System	K103384
Biomet Manufacturing Corp., USA	Taperloc® Complete Stems Taperloc® Complete Microplasty System	K101086, K062994, K103755, K120030, K043537, K921301, K110400

5.6 Device Description:

Latitud™ Hip Replacement System cleared under K172857 consists of modular acetabular cup system, femoral heads, femoral stems and related accessories.

Purpose of this 510(k) is to add following acetabular cup system and femoral stem under previously 510 (k) cleared Latitud™ Hip Replacement System (K172857).

- Latitud™ Triad – Acetabular Cup System
- Latitud™ - Proximally coated Uncemented femoral stem

Latitud™ Triad - Acetabular Cup System

Latitud™ Triad - Acetabular cup system is a modular acetabular cup system. It includes Modular shells, Modular liners and Bone screws.

- **Modular Shell:** Modular shells are intended for uncemented, press fit fixation with prepared acetabulum. They are designed for use with Modular liners. The Modular shells are fabricated from Ti-6Al-4V-ELI (Titanium-6Aluminum-4Vanadium Extra Low Interstitial). Modular shells are available in different sizes. The outer surface of the Modular shell is coated with commercially pure Titanium.

- **Modular Liner:** Modular liners are designed to be used with Modular shell. Modular liners are intended to be articulated with a range of dedicated Cobalt chromium alloy or Biolox® delta Modular femoral heads previously cleared under K172857. Modular liners are fabricated from Highly Cross-Linked Polyethylene (HXLPE). It is available in different sizes.
- **Bone Screw:** Bone screw is used if additional fixation of Modular shell is required. Bone screw is self tapping and is fabricated from Titanium alloy - ELI (Titanium-6Aluminum-4Vanadium Extra Low Interstitial). Bone screw is available in 6.5 mm diameter with different lengths.

Latitud™ - Proximally coated uncemented femoral stem

The proximally coated uncemented femoral stem is fabricated from Titanium alloy – ELI (Titanium-6Aluminum-4Vanadium Extra Low Interstitial) and it is intended to be used with Femoral head (CoCr and Biolox Delta ceramic) previously cleared under K172857. The proximal portion of the stem is coated with commercially pure Titanium with plasma spray method. The proximal coated femoral stem is available in two designs (Standard i.e. full profile design and distally reduced design). Each design is available in different sizes with three neck angles (132° Standard, 132° Lateral, and 128° Standard).

5.7 Indications for use:

The Latitud™ Hip Replacement System is intended for use in total hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is an evidence of sufficient sound bone to fix and support the components.

Total hip replacement is indicated for the following conditions:

- Non-inflammatory degenerative joint diseases including osteoarthritis, post-traumatic arthritis and avascular necrosis.
- Rheumatoid arthritis.
- Congenital hip dysplasia.
- Acute traumatic fracture of the femoral head or neck.
- Certain cases of Ankylosis.
- Dislocation of the hip.
- Correction of functional deformity.
- Revision of failed joint reconstruction or treatment.
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur.

Note:

- The Titanium coated Modular Acetabular Shell is intended for press-fit, uncemented use only.
- The Hydroxyapatite coated Uncemented Femoral Stem is intended for press-fit, uncemented use only.

Meril

- The Proximally coated Uncemented femoral stem is intended for press-fit, uncemented use only.
- The Cemented Femoral stem is intended for cemented use only.
- The Modular Acetabular Liner is intended for use with Modular Acetabular Shell.
- The CoCr Modular Femoral Head is intended to articulate with Modular Acetabular Liner to mate with uncemented stem or cemented stem.
- The Biolox® delta Modular Femoral Head is intended to articulate with Modular Acetabular Liner and to mate with uncemented stem or cemented stem.
- The Bone Screw and Apical Hole Occluder are intended for use with Modular Acetabular shell.
- The Centralizer and Cement Restrictor are intended for use with cemented stem only.

5.8 Comparison of technological characteristics:

The Latitud™ Hip Replacement System is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, device design/technological characteristics, materials, and sterilization method.

5.9 Non clinical Performance data:

Non-clinical testing conducted to evaluate device function/mechanical performance and to demonstrate substantial equivalence.

- Locking Strength of modular acetabular cup and modular liner per ASTM F1820-13.
- Wear test (ASTM F1877-05, ISO 14242-3-2009)
- Impingement Test (ASTM F2582-14)
- Evaluation of torsion properties, pull out properties, driving torque, and self tapping performance of Bone Screw per ASTM F543-13e
- Proximal fatigue test (ISO 7206-6:2013)
- Distal fatigue test (ISO 7206-4:2010)
- Range of motion test (ISO 21535-2007/Amd 1:2016)
- Axial pull-off test (ISO 7206-10:2003)
- Fretting corrosion (ASTM F1875-98; Reapproved 2014)
- Evaluation of Ceramic femoral head includes Burst test, Fatigue test, Post fatigue burst test, Pull-off test (ISO 7206-10:2003) and Torque test (ASTM F1820-13) (Biolox® delta Modular femoral head and Uncemented Stem)
- Ti coating adhesion (shear) test (ASTM F1044-05; Reapproved 2017)e1
- Material Characterization of HXLPE (ASTM F2565-13, ASTM F2759-11, ASTM F648-14, ASTM F2003-15, ISO 5834-3 and ISO 5834-2)

Endotoxin testing has demonstrated that the manufacturing process does not introduce Endotoxin as a bi-product of the manufacturing and cleaning process.

Meril

5.10 Conclusion

Based on performance testing results and similarities in intended use, device design/technological characteristics, materials, and sterilization method, the Latitud™ Hip Replacement System is considered substantially equivalent to the previously cleared predicate devices.