Meril Healthcare Pvt. Ltd.
Yamini Patel
Manager - Regulatory Affairs
Survey No. 135/2/B & 174/2, H1-H3, Meril Park,
Muktanand Marg, Chala
Vapi, Gujarat 396191
India

Re: K222436
Trade/Device Name: Latitud™ Hip Replacement System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, LZO
Dated: April 14, 2023
Received: April 14, 2023

Dear Yamini Patel:

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K222436

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

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

2. **Primary Contact Person:**

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   Manager- Regulatory Affairs
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   Cell: +91 9714408139

3. **Secondary Contact Person:**

   Gayathri Nair
   DGM- Regulatory Affairs / Quality Assurance
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4. **Date prepared:** 09 May 2023

5. **Device information:**

   Proprietary Name: Latitud™ Hip Replacement System

   Common / Usual Name: Hip Joint Prosthesis

Classification name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353

Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350

Product Codes: LPH, JDI, LZO

Device Class: Class II

6. Predicate Devices:

Component	Predicate Device	Manufacturer	510(K) Number
Latitud™ Hip Replacement System (Hydroxyapatite Coated Uncemented Femoral Stem)	Latitud™ Hip Replacement System	Meril Healthcare Pvt. Ltd.	K172857

7. Device Description:

The Latitud™ Uncemented Femoral Stem is fabricated from Titanium alloy - ELI (Titanium-6 Aluminum-4 Vanadium Extra Low Interstitial). It has 12/14 taper at the top which mates with its 510(k) cleared Latitud™ Cobalt Chromium alloy and Biolox® delta Modular femoral head (Cleared under K172857). This stem is implanted without use of bone cement. Stem is coated with Hydroxyapatite (HA) by plasma spraying method. These stems are available in different sizes with neck angles

of 135° standard, 135° lateral and 125° standard (Coxavera). Uncemented Femoral Stem is intended for press-fit uncemented use only.

8. Intended use/Indications:

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 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.

9. Comparison of Technological characteristics:

The subject device is substantially equivalent to legally marketed predicate device with respect to intended use, materials, device design, technological characteristics and manufacturing process including sterilization. The only difference between the subject device and the legally marketed device is the facility where the coating is performed. However, difference in coating facility between subject device and predicate device, does not raise new question of safety and effectiveness

10. Non clinical Performance data:

The subject device was subjected to non-clinical performance testing to evaluate device function/mechanical performance in accordance with applicable ASTM and ISO standard and FDA guidance. The tests include testing on the subject device and the HA powder.

Testing on subject device includes;

- Mechanical tests:
  - Bonding Strength (ASTM F1147-05 (Reapproved 2017)e1)
  - Shear static strength (ASTM F1044-05 (Reapproved 2017)e1)
  - Fatigue Shear test (ASTM F1160-14 (Reapproved 2017)e1)
  - Fatigue bending test (ASTM F1160-14 (Reapproved 2017)e1)

- Morphology tests:
  - Thickness and Porosity (ASTM F1854-15)
  - Roughness Ra/Rt (ISO 4288- 1998)
  - Scanning Electron Microscope (SEM) (FDA Guidance*)
- Chemical tests:
  - Trace elements and heavy metals by ICP (ISO 13779-2 (2018), ISO 13779-3 (2018))
  - Ca/P ratio and Phases and Crystallinity by XRD (ISO 13779-2 (2018), ISO 13779-3 (2018))
  - Fourier-transform infrared spectroscopy (FTIR) (FDA Guidance*)
  - Solubility (ISO 13779-6 (2015))
  - Dissolution (ASTM F1926/F1926M-14)
- Testing on HA powder includes;
  - Granulometry by sieving (ISO 2591-1 (1998))
  - Granulometry by laser diffraction (ISO 24235 (2007))
  - Morphology by Scanning Electron Microscope (SEM) (ISO 13779-6 (2015))
  - Trace elements and heavy metals by ICP (ISO 13779-3 (2018))
  - Ca/P ratio & Phases and Crystallinity by XRD (ISO 13779-3 (2018))
  - Molecular constitution by Fourier-transform infrared spectroscopy (FTIR) (FDA Guidance*)

*FDA guidance document- "510(k) Information needed for Hydroxyapatite coated orthopedic implants. February 1997"

11. Summary of Biocompatibility testing:

- Cytotoxicity Test ISO 10993-5
- Skin Sensitization Study ISO 10993-10
- Acute irritation/Intracutaneous reactivity test ISO 10993-23
- Acute systemic toxicity study ISO 10993-11
- Material mediated pyrogenicity ISO 10993-11, USP General Chapter <151>
- Sub-chronic systemic toxicity test ISO 10993-11

- Bone Implantation Study ISO 10993-6
- Bacterial Reverse Mutation Test ISO 10993-3
- In vitro Mammalian Chromosomal Aberration Test ISO 10993-3

12. Conclusion:

Based on performance testing results and similarities in intended use, manufacturing process, device design/technological characteristics, materials, and sterilization method, the subject device is considered substantially equivalent to the previously cleared predicate device.