July 19, 2018

Meril Healthcare Pvt. Ltd.
℅ Linda Braddon
President & Chief Executive Officer
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K172857
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: June 22, 2018
Received: June 22, 2018

Dear Linda Braddon:

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 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,

Vincent J. Devlin -S

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172857

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 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.

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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 Regulatory Correspondent:

Linda Braddon, Ph.D.
President and CEO
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Meril Healthcare Contact Information:

Bhavik Gondaliya
Manager – Regulatory Affairs
Meril Healthcare Private Limited
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Cell: +91 - 9687604713
E mail: bhavik.gondaliya@merillife.com

5.3 Date prepared: 18 July 2018

5.4 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 Code: LPH, JDI, LZO

Device Class: Class II

5.5 Predicate Devices

Component	Predicate Device	Manufacturer	Submission Number
Acetabular Cup System	Corin's Trinity Acetabular System (Includes Modular shell, Modular liner, Cobalt-Chromium alloy and Biolox® delta Modular Femoral head, Bone screw, Apical Hole occluder)	Corin USA	510 k Number: K110087, K103120, K130343 : For Shell, HXLPE liner, Cobalt-Chromium alloy and Biolox® delta Modular Femoral Head K093472: For Bone screw and Apical hole occluder
	Depuy's Pinnacle Acetabular System	DePuy Orthopaedics, Inc., USA	510k Number: K000306
Uncemented femoral stem	Depuy's Corail® HA Coated hip Stem	Depuy Orthopaedics France S.A.S	510 k Number: K042992
Cemented femoral stem	Stryker's Exeter® Hip Stem (Includes Cemented stem, Cement restrictor and Centralizer)	Stryker®, Howmedica Osteonics, USA	510 k Number: K110290: Stem K980843: Cement restrictor K974054, K960258: Centralizer
	Distal centralizer of Natural hip system	Intermedics Orthopedics Inc.	K960258: Centralizer

5.6 Device Description:

The Latitud™ Hip Replacement System consists of following components:

- **Acetabular Cup System**
  - Modular Shell / Cup
  - Modular Liner
  - Cobalt Chromium Modular Femoral Head
  - Biolox® delta Modular Femoral Head

- **Femoral Stem**
  - Uncemented Femoral Stem
  - Cemented Femoral Stem

- **Accessories (Sub components)**
  - Bone Screw
  - Apical Hole Occluder
  - Centralizer
  - Cement Restrictor

Acetabular Cup System

Acetabular cup system is a modular acetabular replacement system consisting of a range of Modular Shells, Modular Liners, Cobalt chromium alloy and Biolox® delta Modular Femoral Heads. The Modular Shells are designed for use with dedicated sizes of Modular Liners articulating with a range of dedicated Cobalt chromium alloy and Biolox® delta Modular Femoral Heads.

Modular Shell: Modular Shell is intended for uncemented, press fit fixation with prepared acetabulum. They are designed for use with Modular liners. The Modular shell is fabricated from Ti-6Al-4V-ELI (Titanium-6Aluminum-4Vanadium Extra Low Interstitial). Modular shell is available in different sizes. The outer surface of the Modular shell is coated with commercially pure Titanium. Two/Three screw holes are provided in Modular shell for additional immediate fixation with bone by means of Bone screws. A threaded apical hole is provided to attach instruments for surgical insertion. After fixation of Modular shell, apical hole will occlude by Occluder.

Modular Liner: Modular liner is designed to be used with Modular shell and articulate with a range of dedicated Cobalt chromium alloy or Biolox® delta Modular femoral heads. Modular liner is fabricated from Highly Cross-Linked Polyethylene (HXLPE). It is available in different sizes.

Cobalt chromium Modular Femoral Head: Modular femoral head fabricated from cobalt chromium alloy is designed to mate with 12/14 taper of femoral stem through taper-locking arrangement and to articulate with Modular liner. It is available in different sizes with different offsets.

Biolox® Delta Modular Femoral Head: Modular femoral head fabricated from ceramic material **(**Biolox® delta, by CeramTec, Germany) is designed to mate with 12/14 taper of femoral stem through taper-locking arrangement and to articulate with Modular liner. It is available in different sizes with different offsets.

Femoral Stem

Uncemented Femoral Stem: The Uncemented femoral stem is fabricated from Titanium alloy - ELI (Titanium-6Aluminum-4Vanadium Extra Low Interstitial). It has 12/14 taper at the top which mates with Cobalt chromium alloy and Biolox® delta Modular femoral head. 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 three different neck angles. Uncemented femoral stem is intended for press-fit uncemented use only.

Cemented Femoral Stem: Cemented femoral stem is fabricated from High Nitrogen Stainless Steel (HNSS). It has 12/14 taper trunnion at the top which mates with Cobalt chromium alloy and Biolox® delta Modular femoral head. This stem is implanted with use of bone cement. These stems are available in different sizes with two different offsets. Cemented stem is intended for cemented use only.

Accessories (Subcomponents):

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.

Apical Hole Occluder: Apical hole occluder is provided to occlude the apical hole after fixation of the Modular shell in acetabulum. Apical hole occluder is fabricated from Titanium alloy - ELI (Titanium-6Aluminum-4Vanadium Extra Low Interstitial). Apical hole occluder is available in one size.

Centralizer: Centralizer is used for correct positioning of Cemented stem in medullary canal of femur. Centralizer is fabricated from Ultra High Molecular Weight Polyethylene (UHMWPE). Centralizer is designed to be used with Cemented stem only. Centralizer is offered in two sizes.

Cement Restrictor: Cement restrictor is used to occlude and seal intramedullary canal in order to generate sufficient pressure to enhance cement penetration and to prevent distal cement leakage. Cement restrictor is designed to be used with Cemented stem only. Cement restrictor is fabricated from Ultra High Molecular Weight Polyethylene (UHMWPE). Cement restrictor is provided in two sizes.

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.
- 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:

The components of Latitud™ Hip Replacement System were subjected to following non-clinical performance testing to evaluate device function/mechanical performance.

- Axial Disassembly (Push out) test (ASTM F1820-2013)
- Offset pull out (Lever Out) test Disassembly (ASTM F1820-2013)
- Torque Out Disassembly test (ASTM F1820-2013)
- Ti coating adhesion (shear) test (ASTM F1044-05; Reapproved 2011)
- Wear test (ISO 14242-3-2009 & ISO 14242-2-2014)
- Impingement test (ASTM F2582-14) (Acetabular Cup System)
- Fretting Corrosion (ASTM F1875-98; Reapproved 2014) (Uncemented Femoral Stem & Cobalt chromium Modular femoral head)
- Axial pull-off test (ISO 7206-10-2003) (Uncemented Femoral Stem & Cobalt chromium Modular femoral head)
- Proximal fatigue test (ISO 7206-6-2013) (Uncemented Femoral Stem)
- Distal fatigue test (ISO 7206-4-2010) (Uncemented Femoral Stem)
- Range of motion test (ISO 21535-2007)
- HA coating adhesion (shear) test (ASTM F1044-05, Reapproved-2011)
- Proximal fatigue test (ISO 7206-6-2013) (Cemented Femoral Stem)
- Distal fatigue test (ISO 7206-4-2010) (Cemented Femoral Stem)
- Fretting Corrosion (ASTM F1875-98; Reapproved 2014) (Cemented Femoral Stem and Cobalt chromium Modular femoral head)
- Axial pull-off test (ISO 7206-10-2003) (Cemented Femoral Stem & Cobalt chromium Modular femoral head)
- Bone Screw Torsion properties (ASTM F543-13e)
- Bone Screw Pull out properties (ASTM F543- 13e)
- Bone Screw Driving torque test (ASTM F543- 13e)
- Bone Screw Self tapping performance (ASTM F543- 13e)
- Burst test, Fatigue test, Post fatigue burst test, Pull-off test for Biolox® delta Modular femoral head and Uncemented Femoral Stem (ISO 7206-10)
- Torque test for Biolox® delta Modular Femoral head (ASTM F1820) / Torsional resistance test (ISO 7206-13)
- Burst test for Biolox® delta Modular femoral head and Cemented Femoral Stem

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

Latitud™ Hip Replacement System is subjected to 14 day USP sterility testing and USP Endotoxin testing prior to release.

Meril Healthcare Pvt. Ltd. confirms that the Bacterial Endotoxin Test [(BET)/LAL test] will be conducted on final sterilized device of every batch prior to releasing to US market.

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.