November 18, 2022

Meril Healthcare Pvt. Ltd.
Neelam Desai
Senior Manager- Regulatory Affairs
Survey No. 135/2/B & 174/2, H1-H3, Meril Park
Muktanand Marg, Chala
Vapi, Gujarat 396191
INDIA

Re: K222816
Trade/Device Name: Opulent TiNbN Coated Knee
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: September 11, 2022
Received: September 19, 2022

Dear Neelam Desai:

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,

Ting Song -S

Ting Song, 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)*
K222816

Device Name
Opulent TiNbN Coated Knee

Indications for Use *(Describe)*
The Opulent TiNbN Coated Knee is indicated for the following:
• Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, and polyarthritis.
• Correction of functional deformities.
• Post-traumatic loss of knee join contour, particularly when there is patellofemoral erosion, dysfunction, and/or prior patellectomy.
• Moderate valgus, varus, or flexion trauma.
• Knee fractures untreatable by other methods.
• Revision surgery where sufficient bone and soft tissue integrity are present.

The Opulent TiNbN Coated Knee is intended for cemented use only. This device is for single use 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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
Ground & First Floor, Survey No.173/4 & First Floor H1-H3,
Meril Park, Survey No. 135/2/B & 174/2,
Muktanand Marg, Chala,
Vapi - 396 191, Gujarat, INDIA

### 5.2 Primary Contact Person:

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Senior Manager- Regulatory Affairs
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### 5.3 Secondary Contact Person:

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Deputy General Manager - Regulatory Affairs/ Quality Assurance
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### 5.4 Date prepared: September 11th, 2022

### 5.5 Device information:

| | |
|---|---|
| **Proprietary Name:** | Opulent TiNbN Coated Knee |
| **Common / Usual Name:** | Total Knee prosthesis |
| **Classification name:** | Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis |
| **Regulation Number:** | 21 CFR 888.3560 |

**Product Code:** JWH

**Device Class:** Class II

### 5.6 Predicate Device

| Subject device | Equivalent device category | Manufacturer | Trade name | 510(k) number |
|---|---|---|---|---|
| Opulent TiNbN Coated Knee | Predicate device | Meril Healthcare Pvt. Ltd. | Opulent TiNbN Coated Knee | K212839 |

### 5.7 Device Description:

The Opulent TiNbN Coated Knee comprises of Femoral Component and Tibial Component as described below,

- Femoral Knee Component CR and PS (Left and Right)
- Tibial Component (Tibial Base Plate)

Each of these components is described below.

#### 5.7.1 Femoral Component

The Femoral Component is fabricated from Cobalt-Chromium-Molybdenum (Co-Cr-Mo), coated with Titanium Niobium Nitride (TiNbN). The Femoral Component is available in two designs: Cruciate Retaining (CR) and Posterior Stabilized (PS). Each of these designs is further classified into Left and Right configurations. Each Left and Right configuration is available in eight different sizes (A to H) based on Anterior/Posterior (A/P) and Medial/Lateral (M/L) dimensions. Thus, a total of thirty two (32) models are available for the Femoral Component.

#### 5.7.2 Tibial Component (Tibial Base Plate)

The Tibial Base Plate is fabricated from Cobalt-Chromium-Molybdenum coated with TiNbN. The tibial base plate is available in eight different sizes from 1 to 8 based on Anterior/Posterior (A/P) and Medial/Lateral (M/L) dimensions.

### 5.8 Indication for use:

The Opulent TiNbN Coated Knee is indicated for the following:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, and polyarthritis.
- Correction of functional deformities.

- Post-traumatic loss of knee join contour, particularly when there is patellofemoral erosion, dysfunction, and/or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods.
- Revision surgery where sufficient bone and soft tissue integrity are present.

The Opulent TiNbN Coated Knee is intended for cemented use only. This device is for single use only.

**5.9 Comparison of technological characteristics:**

The subject device is substantially equivalent to FDA cleared Opulent TiNbN Coated Knee (K212839) from Meril Healthcare Pvt. Ltd. Both have same intended use, manufacturing process, device design/technological characteristics, materials, packaging and sterilization method. There is no technological difference between the subject device and the predicate device.

**5.10 Non clinical Performance data:**

The subject device was subjected to following non clinical performance testing to evaluate device function and mechanical performance.

a) Coating characteristics of TiNbN Coating
   - Coating thickness
   - Coating hardness
   - Coating roughness
   - Coating adhesion strength
   - Colour (visual inspection)

b) Coating chemical composition and SEM EDS

c) Wear resistance

**5.11 Summary of Biocompatibility testing**

- Cytotoxicity test ISO 10993-5
- Skin Sensitization study ISO 10993-10
- Acute irritation/Intracutaneous reactivity test ISO 10993-10
- 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

## 5.12 Conclusion

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