November 16, 2021

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

Re: K212839
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: August 31, 2021
Received: September 7, 2021

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, Ph.D., R.A.C.
Assistant Director
Knee Arthroplasty Devices Team
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)*
K212839

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.

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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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Assistant Manager- Regulatory Affairs

Meril Healthcare Private Limited

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5.3 Secondary Contact Person:

Gayathri Nair

Senior Manager- Regulatory Affairs/ Quality Assurance

Meril Healthcare Private Limited

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5.4 Date prepared: August 28th, 2021

5.5 Device information:

Proprietary Name:	Opulent TiNbN Coated Knee
Common / Usual Name:	Total Knee prosthesis
Classification name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Regulation Number: 21 CFR 888.3560

Product Code: JWH

Device Class: Class II

5.6 Predicate Devices

Subject device	Equivalent device category	Manufacturer	Trade name	510(k)
Opulent - TiNbN Coated Knee	Predicate device	Maxx Orthopedics Inc., USA	Freedom® - TiNbN Coated Knee	K200912
	Reference device	Meril Healthcare Pvt. Ltd.	Destiknee Total Knee System	K160771 and K172936

5.7 Device Description:

The Opulent TiNbN Coated Knee comprises of a 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. These components are compatible with previously cleared components of the Destiknee Total Knee System (e.g., patellae, tibial inserts).

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.

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 Opulent TiNbN Coated Knee is substantially equivalent to FDA cleared Freedom TiNbN Coated Knee (K200912) from Maxx Orthopedics Inc., USA. Both have same indications, design, materials, packaging, surgical implantation technique, intended use, TiNbN coating, and the sterilization method. There is no technological difference between the subject device and the predicate device. Furthermore, subject device is also substantially equivalent to FDA cleared Destiknee Total Knee System (K160771 and K172936) with respect to CoCr Alloy base material, intended use, design, packaging, surgical implantation technique and sterilization method.

Meril

5.10 Non clinical Performance data:

The representative samples with the TiNbN Coating, were subjected to the following mechanical tests to evaluate device function and performance of the coating for its intended use:

a) Wear Resistance
b) Coating Chemical Composition
c) Coating Thickness
d) Coating Hardness
e) Coating Adhesion Strength
f) Roughness
g) Metal Ion Analysis

The tests 'b' through 'g' listed above were performed by DOT, GmbH on the representative samples with the TiNbN coating.

Moreover, the below listed mechanical tests are leveraged from the testing performed on *Freedom® Total Knee System **(**K082019 Femoral Component (PS), K090411 Tibial Base Plate Component and K091280 Femoral Component (CR) and *Destiknee Total Knee System (K172936 and K160771)). The cleared devices are identical to the subject devices, except that the subject devices have a TiNbN coating on the surface. However, the TiNbN coating does not have any effect on these tests and hence, the testing performed on the cleared uncoated Freedom® and Destiknee devices can be leveraged for the subject devices.

- Tibial-Femoral Contact Area Stress and Surface Stress Testing
- Tibial-Femoral Constraint Testing
- Range of motion analysis
- Patello-Femoral Lateral Subluxation
- Patello-Femoral Contact Area Stress and Surface Stress Testing
- Tibial Tray Locking Mechanisms Testing
- Finite Element Analysis of Tibial Tray
- Tibial base plate component fatigue testing
- Tibial Post Fatigue Strength (static and fatigue)

*Meril Healthcare Pvt. Ltd., India (Meril) and Maxx Orthopedics, Inc. (Maxx) have entered into an agreement, under which Meril acts as contract manufacturer and distributor for the Freedom® Total Knee System, which includes the Freedom® TiNbN Coated Knee. Meril is also the designer and developer of the Destiknee™ Total Knee System and their version of the TiNbN coated knee – the Opulent TiNbN Coated Knee. Maxx has licensed the design for its Freedom® Total Knee System to Meril, which Meril has used to create the Destiknee™ and Opulent TiNbN Coated Knee. Therefore, the Destiknee™ and Opulent TiNbN Coated Knee is identical to the Freedom® Total Knee System and Freedom® - TiNbN Coated Knee with respect to intended use, device design, materials, technological characteristics, and method of sterilization. Therefore, all testing on the Destiknee™, Freedom® devices and Opulent devices is applicable to each other.

5.11 Conclusion

The indications for use and fundamental scientific technology of the subject devices are identical to the predicate devices. Design features, materials information, predicate testing and analysis data provided in this premarket notification adequately support the substantial equivalence of Opulent TiNbN Coated Knee.