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

November 30, 2017

Re: K172936
Trade/Device Name: Destiknee™ Total Knee System
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 27, 2017
Received: October 04, 2017

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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)*

K172936

Device Name
DestikneeTM Total Knee System

Indications for Use *(Describe)*

The DestikneeTM Total Knee System is indicated for patients with severe knee pain and disability due to:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods.

The Destiknee™ Total Knee System 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
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
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, GA, 30188
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Meril Healthcare Contact Information:

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Manager- regulatory Affairs
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Meril

5.3 Date prepared: 27, September 2017

5.4 Device information:

Proprietary Name: Destiknee™ Total Knee System

Common / Usual Name: Total Knee Replacement

Regulation name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Product Code: JWH

Device Class: Class II

5.5 Predicate Devices

Component	Predicate Device	Manufacturer	Submission Number
Femoral Component, Tibial Component (Tibial Base Plate and Tibial Articular Surface), All Poly Tibial Component, All Poly Patella	Destiknee™ Total Knee System	Meril Healthcare Pvt. Ltd.	510(k) Number: K160771

5.6 Device Description:

The Destiknee™ Total Knee System is a system of components intended to replace the Femoral, Tibial and Patella articular surfaces of the knee joint. The components are

available in many styles and sizes and are manufactured from metallic and non-metallic materials.

The Destiknee™ Total Knee System was originally cleared under 510(k): K160771. The purpose of current submission is to add Tibial Base Plate (size 7 and size 8) and All Poly Patella (size 37mm and 40mm) in Destiknee™ Total Knee System.

5.7 Indications for Use:

The Destiknee™ Total Knee System is indicated for patients with severe knee pain and disability due to:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods.

The Destiknee™ Total Knee System is intended for cemented use only. This device is for single use only.

5.8 Comparison of Technological characteristics:

The Destiknee™ Total Knee system is substantially equivalent to the previously cleared predicate device based on similarities in intended use, device design/technological characteristics, materials and sterilization method.

5.9 Non clinical Performance data:

The components of Destiknee™ Total Knee System were subjected to following non-clinical performance testing to evaluate device function/ mechanical performance.

- Fatigue test of Tibial Base Plate (ASTM F1800-12; ISO 14879-1:2000)

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

Destiknee™ Total Knee 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 Destiknee™ Total Knee System is considered substantially equivalent to the previously cleared predicate device.