DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 19, 2016

Meril Healthcare Private Limited
% Jon Ward
President and CEO
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd.
Apollo Beach, Florida 33572

Re: K160771
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: November 14, 2016
Received: November 14, 2016

Dear Jon Ward:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K160771

Device Name: Destiknee™- Total Knee System

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.

Prescription Use: X AND/OR Over-The-Counter Use: ____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IFNECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

5.2 Contact Person:

Umesh Sharma
Deputy General Manager (DGM)
Meril Healthcare Private Limited
H1-H3, Meril Park, Survey No. 135/2/B & 174/2,
Muktanand Marg, Chala, Vapi - 396 191, Gujarat, INDIA
Phone: +91 - 2603063811
Mobile: +91 – 9904805571
Fax: +91 260-3052125
E mail: umesh.sharma@merillife.com

5.3 Regulatory Correspondent:

Jon Ward
President and CEO
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd.
Apollo Beach, FL 33572
Phone: 813-645-2855 x104
Fax: 813-645-2856
Email: wardjp@ajwtech.com

5.4 Date prepared: 14Dec2016

5.5 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.
Review Panel	Orthopaedic
Regulation Number:	21 CFR 888.3560
Product Code:	JWH
Device Class:	Class II

5.6 Predicate Device

a. The Freedom® - Total Knee System (K082019, K090411, K091280)

5.7 Device Description:

The Destiknee™ Total Knee System consists of following components.

- Femoral Component
- Tibial Component which is available in following two designs
  - Metal Backed Tibial Component which consists of Tibial Base Plate and Tibial Articular Surface (viz. Tibial Liner)
  - All Poly Tibial Component (viz. All Poly) and
- All Poly Patella Component

Each of these components are described below.

1. Femoral Component

Femoral Component is fabricated from Cobalt-Chromium-Molybdenum alloy and is intended for cemented application to replace the articulating surface of the distal femur in a measured resection technique.

The Femoral Component is available in two designs viz. Posterior Stabilized (PS) and Cruciate Retaining (CR).Each design is classified into Left and Right configurations. Each Left and Right configuration is available in eight different sizes.

2. Tibial Component

Tibial Component is available in following two designs:

a) Metal Backed (modular/two pieces)

b) All Poly (non-modular/single piece)

Metal backed design of Tibial component is modular two piece design viz. Tibial Base Plate and Tibial Articular Surface (viz. Tibial Liner).

The Tibial Base Plate is fabricated from Cobalt-Chromium-Molybdenum alloy and is intended for use with the Tibial Liner for cemented application to replace the articulating surface of the proximal tibia in a measured resection.

Tibial Liner is fabricated from industry standard Ultra High Molecular Weight Polyethylene (UHMWPE) and is intended for use with the Tibial Base Plate to replace the articulating surface of the proximal tibia in a measured resection. It has a locking mechanism on the peripheral edges of the distal surface to lock into the Tibial Base Plate.

The Tibial Liner is available in two designs viz. Posterior Stabilized (PS) and Cruciate Retaining (CR).Each PS and CR designs are available in 14 configurations. Each configuration is further available in four different thickness viz. 9mm, 11mm, 14mm and 17mm.

All poly design is a non modular single piece design viz. All Poly Tibial Component (viz. All Poly)fabricated from industry standard Ultra High Molecular Weight Polyethylene (UHMWPE) and is intended for cemented application to replace the articulating surface of the proximal tibia in a measured resection. All Poly is available in two designs viz. Posterior Stabilized (PS) and Cruciate Retaining (CR).

Each PS and CR designs are available in 12 configurations. Each configuration is available in five different thickness viz. 9mm, 11mm, 14mm, 17mm and 20mm.

All Poly Patella Component is fabricated from industry standard Ultra High Molecular Weight Polyethylene (UHMWPE). It is available in a symmetric single radius design. The symmetrical design is available in 4 diameters.

All materials used in Destiknee™ Total Knee System meet ASTM standards for implants, viz. ASTM F648 "Standard Specification for Ultra High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants" and ASTM F-75 "Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting alloy for Surgical Implants (UNS R30075)".

5.8 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.

5.9 Comparison of Technological characteristics:

The Destiknee™ Total Knee system is identical to the predicate device with respect to intended use, device design, materials, and method of sterilization.

All the necessary performance tests to determine the material and mechanical characteristics have been performed on predicate device viz. Freedom® Total Knee System.

5.10 Non clinical Performance data:

Destiknee™ Total Knee System is identical to the predicate device viz. Freedom® Total Knee System with respect to intended use, device design, materials, and method of sterilization.

All necessary performance tests to determine the material and mechanical characteristics have been performed on identical device. Performance testing includes: endurance properties (cyclical testing), stability, surface stress, kinematic range of motion.

There have been no adverse event reports associated with the Destiknee™ Total Knee System and no recalls have been initiated.

5.11 Conclusion

The Destiknee™ Total Knee System is identical to predicate device with respect to intended use, device design, materials and method of sterilization. Therefore, Destiknee™ Total Knee System is considered substantially equivalent to the predicate device.