



October 26, 2017

MORIA S.A.
c/o Cherita James
Regulatory Consultant
M Squared Associates, Inc
901 King Street, Suite 200
Alexandria, VA 22314

Re: K172994
Trade/Device Name: EPI K Console
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: September 26, 2017
Received: September 27, 2017

Dear Cherita James:

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 (DICE) 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 (DICE) 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,


Denise L. Hampton -S

for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172994

Device Name

Epi-K

Indications for Use (Describe)

The Epi-K is intended for use in the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on denuded cornea.

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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510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Moria Evolution 3E Console Special 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

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Date of Submission: October 25, 2017

Proprietary Name: Moria Evolution 3E Console

Common Name: Keratome power unit

Regulatory Class: I

Regulation: 886.4370 keratome, AC powered

Product Codes: HNO

Predicate Device: K043183 Epi-K

Device Description : The Evolution 3E Console includes pumps for producing vacuum for use with a keratome in the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on denuded cornea.

The Evolution 3E Console power unit has been designed to operate the keratome by means of electric motor or turbine.

The front panel includes several displays and features:

- Various indicators-Vacuum level, low vacuum, pump indicator, battery level, mains power, manual mode
- Various displays- Operating mode, pressure status
- Connection for the motorized handpieces- Epi-K connector, One Use-Plus connector, M2 connector
- Turbine and aspiration tubing connectors
- Low vacuum, mode selection, speed switches

The back panel includes connectors for footswitches and battery charger

- Control knob to adjust gas pressure to the turbine
- Connectors for Nitrogen/Air supply, Main Power Supply and Footpedal
- Mains power switch, Residual Gas Drain Switch
- Volume adjustment for Epi-K Footpedal Steps
- Device required labeling

All accessory components in contact with the patient are unchanged in regard to materials and manufacturing/processing methods from the predicate device. The changes in design and function between the Evolution 3E Console power unit and predicate device have not altered sterilization, biocompatibility, or expiration date.

Indication for Use: The Epi-K is intended for use in the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on denuded cornea.

Summary of Technological Characteristics: The Evolution 3E Console modifications include a change from a battery powered device to a Mains powered device with a battery back-up, as well as minor software revisions.

Summary of Nonclinical Testing: The verification and validation activities, as identified by the risk analysis including verification of back-up battery performance, transformer power supply, vacuum/turbine and connection performance, verification of performance with accessory components of the with keratome systems, and software verification and validation were conducted to ensure that the modified device is as safe and effective as

K172994

the predicate device, have been completed and demonstrate that the predetermined acceptance criteria have been met. The Evolution 3E Console demonstrates conformity to the following standards:

- IEC 60601-1:2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Substantial Equivalence Discussion:

Similarities and Differences

There is no change to the intended use or indications for use as a result of modifications to the console. The console power unit functions and operating principles are the same as the predicate device. All compatible components are the same as the predicate device. The Evo3E Console will produce the same clinical outcomes as the predicate device.

The Evolution 3E differs from the Evo2 console cleared in K043183 in the power source coming from either a mains power supply or back-up battery system when compared to the Evo2 being battery operated only. The EVO2 battery was charged via an external battery charger connected to a wall electrical supply while not in use, and disconnected during surgery. The Evo3E console operates while connected to the wall supply, and the battery back-up is available in the event of power loss at the wall supply.

Electrical safety, EMC testing, and applicable collateral standards confirm that the Evo 3E performs as safely for its intended use in the intended environment as the predicate device. The Declarations of Conformity with Design Controls provided confirm that applicable testing was conducted and support the equivalent operation of the Evo 3E Console when compared to the predicate. Subsequent software updates have also been implemented to the Evo 3E Console, and have been verified to perform as intended.

Conclusion: The Evolution 3E Console does not alter the fundamental scientific technology of the Epi-K device because it does not change the operating principle. The modifications to the console do not impact the device for its intended use in the

K172994

separation of the epithelium from the cornea in preparation for subsequent surgical procedures on denuded cornea.

The modified Evolution 3E Console of the Epi-K microkeratome described in this submission is substantially equivalent to the predicate.