March 15, 2018

Miramar Labs, Inc.
Cynthia Kada
Sr. Director, QA
2790 Walsh Avenue
Santa Clara, California 95051

Re: K180396
Trade/Device Name: miraDry System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY, OUB, MWY
Dated: February 12, 2018
Received: February 13, 2018

Dear Cynthia Kada:

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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K180396

Device Name
miraDry System MD4000

Indications for Use *(Describe)*
The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV.
Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.
When used with the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor.

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.

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2. 510(k) SUMMARY

Classification:	Class II (special controls)
Classification No.:	21 CFR 878.4400
Classification Name:	Electrosurgical cutting and coagulation device and accessories.
Product Code(s):	OUB, NEY, MWY
Common Name:	Instrument for Treatment of Hyperhidrosis System, Ablation, Microwave And Accessories System, Microwave, Hair Removal
Trade Name	miraDry MD4000 System
Predicate Device	miraDry MD 4000 System K160141
Submitter:	Miramar Labs, Inc. 2790 Walsh Avenue Santa Clara, CA 95051, USA Tel: 408-940-8700 Fax: 408-940-8795
FDA Registration No.	3008082710
Contact:	Cynthia Kada
Date:	February 12, 2018

PURPOSE OF SUBMISSION

The purpose of this Special 510(k) submission is to modify how the treatment bioTip component of the miraDry System is provided to the User. The intended use of the modified device, as described in the labeling, has not changed as a result of this modification.

DEVICE DESCRIPTION

The miraDry MD4000 System is a microwave device designed to heat tissue located at the dermal- hypodermal interface where the axillary sweat and odor glands and hair bulbs reside using a surface contact applicator. The miraDry MD4000 System consists of:

- MD4000-MC Console;
- MD4000-HP miraDry Handpiece; and
- MD4000-BT miraDry bioTip that snaps onto the Handpiece

The miraDry MD4000 System also includes the following Class I components/accessories:

- MD4000-TS template system, a required component for the miraDry treatment
- MD4000-PK priming kit; and
- MD4000-BT-DE demonstration bioTip.

The MD4000-PK priming kit and the non-sterile "demo" bioTip are required when the system is initially set up at a user facility. Optional accessories include an armrest and disposable ice packs.

The MD4000-MC Console is a software-driven device, which contains circuit boards, a microwave generator, integrated vacuum and cooling systems, and an integrated touch-screen user interface.

The non-invasive miraDry Handpiece is specifically designed to deliver microwave energy to the skin at specified frequency and power levels. The proximal end of the Handpiece has a cable bundle and a console connector that supplies the energy and cooling to the Handpiece. The distal end of the Handpiece has a single patient use disposable, the miraDry bioTip, which contacts the underarm skin of the patient.

DEVICE MODIFICATION

As described in K160141, the bioTip is disposable and for single patient use, and is provided sterile. The only change to the miraDry MD4000 system cleared under K160141 that is the subject of this Special 510(k) involves supplying the disposable bioTips to the user as clean and non-sterile for single patient use only. The intended use of the modified device, as described in the labeling, has not changed as a result of this modification.

INDICATIONS FOR USE

The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV.

Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

When used with the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The miraDry MD4000 System described and cleared in 510(k) number K160141 serves as the predicate device for this premarket notification. The miraDry MD4000 System that is the subject of this Special 510(k) has the same technological characteristics and intended use as the device described and cleared in 510(k) number K160141. Furthermore, there have been no changes in design, component materials, chemical composition, or energy source, since FDA's clearance of K160141.

Therefore, the miraDry System MD4000 remains substantially equivalent to the predicate device currently marketed under the Federal Food, Drug and Cosmetic Act except for one characteristic: the condition of use of the bioTips. This difference is rendered inconsequential by the "single patient use" and disposable nature of the bioTips that eliminates the risk of cross contamination between patients. Summarized in the substantial equivalence tables below are the key technological characteristics and indications for use of the miraDry System compared to the predicate device identified in this Special 510(k).

miraDry System Substantial Equivalence Comparison Table

Characteristics miraDry System	Predicate Device miraDry MD4000 K160141	Modified Device miraDry MD4000	Comparison
Device Class	II	II	Same
Energy Type	Microwave	Microwave	Same
Mode of Action	Generation of localized heat	Generation of localized heat	Same
Product Code	NEY, OUB, MWY	NEY, OUB, MWY	Same

Characteristics miraDry System	Predicate Device miraDry MD4000 K160141	Modified Device miraDry MD4000	Comparison
Indications for Use	The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. When used with the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor.	The miraDry System MD4000 is indicated for use in the treatment of primary axillary hyperhidrosis plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. When used with the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor.	Same
Function	Heat absorption by tissue located at the dermal-hypodermal interface where the axillary sweat (wetness and odor) glands and hair bulbs reside	Heat absorption by tissue located at the dermal-hypodermal interface where the axillary sweat (wetness and odor) glands and hair bulbs reside	Same
Overall System structure	Microwave source/amplifier, coolant supply system, operator interface, and microwave, electrical and coolant lines that connect to the applicator	Microwave source/amplifier, coolant supply system, operator interface, and microwave, electrical and coolant lines that connect to the applicator	Same
Key Components	Console, Handpiece, disposable bioTip	Console, Handpiece, disposable bioTip	Same
Console Control Mechanism	Electronic user interface	Electronic user interface	Same
Coolant usage	Delivers cooling to the skin surface	Delivers cooling to the skin surface	Same

miraDry System bioTip Component Substantial Equivalence Comparison Table

Characteristics of bioTip	Predicate Device miraDry MD4000 K160141	Modified Device miraDry MD4000	Comparison
Materials	Polyurethane, Thermoplastic Elastomer (TPE), Polycarbonate	Polyurethane, Thermoplastic Elastomer (TPE), Polycarbonate	Same
Biocompatible	Yes	Yes	Same
Packaging Configuration	Thermo-formed (PETG) plastic tray with Tyvek lid	Thermo-formed (PETG) plastic tray with Tyvek lid	Same
Treatment Condition	Sterile	Clean, non-sterile	Change to how it is provided
Condition of Use	Single patient use, disposable	Single patient use, disposable	Same

SUMMARY OF VERIFICATION AND VALIDATION ACTIVITIES

The Special 510(k) for this device modification to the cleared miraDry System (K160141) utilized Miramar Labs established quality system and design control requirements in accordance with the Quality System Regulation (21 CFR 820).

Miramar Labs Inc. declares conformance to design controls in making this change and utilized the following risk based assessments:

1. Risk assessment including Hazard Analysis
2. Complaints incidence and review
3. Manufacturing environment and process evaluation including bioburden testing and monitoring trends
4. Instructions for Use
5. User interface and clinician user feedback

Risk control measures were focused on manufacturing environment, user interface evaluation, and postmarket surveillance and user feedback. No new risks were identified as a result of this change.

CONCLUSION

Based on all information in this Special 510(k), the miraDry MD4000 System and accessories is substantially equivalent to the identified predicate device currently marketed under the Federal Food, Drug and Cosmetic Act. The safety and effectiveness of the device modification are reasonably assured with no new or increased risks justifying 510(k) clearance.