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

June 19, 2015

Miramar Labs Incorporated
Dr. Kathy O'Shaughnessy, Ph.D.
Vice President, Clinical/Regulatory/Quality Assurance
2790 Walsh Avenue
Santa Clara, California 95051

Re: K150419
Trade/Device Name: MiraDry System MD4000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OUB, NEY, MWY
Dated: May 5, 2015
Received: May 6, 2015

Dear Dr. O'Shaughnessy:

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" (21CFR 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,

Jennifer R. Stevenson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150419

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

GENERAL INFORMATION

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 System MD4000
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:	Kathy O'Shaughnessy, PhD VP, Clinical/Regulatory/Quality
Date prepared:	06/16/15

INTENDED 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.

PREDICATE DEVICES

The miraDry System MD4000 (K131162).

REFERENCE DEVICE

The Microwave Delivery System Model MMC-330 (K991456).

DEVICE DESCRIPTION

The miraDry System MD4000 is a microwave device designed to heat tissue located at the dermal- hypodermal interface where the axillary sweat glands and hair bulbs reside using a surface contact applicator. The miraDry System MD4000 consists of: the MD4000-MC Console; the MD4000-HP miraDry Handpiece; and a disposable, sterile MD4000-BT miraDry bioTip that snaps onto the Handpiece to provide a sterile protective cover.

As described in K131162, the miraDry System MD4000 also includes Class I components/accessories. The MD4000-TS template system is a required component for the miraDry treatment as well as the MD4000-PK priming kit. The MD4000-PK priming kit is 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 has a sterile, disposable barrier, the miraDry bioTip, which contacts the patient.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The miraDry System MD4000 with the revised, expanded indication to include underarm hair removal is substantially equivalent to the miraDry System MD4000 as previously cleared for sweat reduction. The subject and predicate device have the same fundamental technology, design, and method of usage. A comparison of the two devices is shown in Table 1 below.

Table 1. Substantial Equivalence Comparison Table.

Characteristics	Predicate Device miraDry MD4000	Subject Device miraDry MD4000
510(k)	K131162	K150419
Device Class	II	II
Energy Type	Microwave	Microwave
Mode of Action	generation of localized heat	generation of localized heat
Product Code	NEY, OUB	NEY, OUB, MWY
Indications for Use	The miraDry System is indicated for use in the treatment of primary axillary hyperhidrosis. Note: The miraDry System is not indicated for use in the treatment of hyperhidrosis related to other body areas or generalized hyperhidrosis.	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.
Function	Heat absorption by tissue located at the dermal- hypodermal interface where the axillary sweat glands reside	Heat absorption by tissue located at the dermal- hypodermal interface where the axillary sweat glands and hair bulbs reside
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
Key Components	Console, handpiece, disposable applicator tip	Console, handpiece, disposable applicator tip
Console Control Mechanism	electronic user interface	electronic user interface
Coolant usage	Delivers cooling to the skin surface	Delivers cooling to the skin surface

NON-CLINICAL TESTING

There was no additional non-clinical testing that was completed, as the device being used is the same as the cleared device (miraDry System MD4000, cleared under K131162).

CLINICAL TESTING

The safety and effectiveness of the clinical application of the miraDry System MD4000 for sweat reduction was demonstrated in prior clinical studies. The performance for underarm hair reduction was demonstrated in a clinical trial of 56 subjects.

The primary objective of this study was to quantify hair reduction in the axillae after treatment(s) with the miraDry System MD4000. The study device was used in the same manner as the commercially available technique cleared by the FDA for the treatment of primary axillary hyperhidrosis, as described in the User Manual.

The study was conducted at three private dermatology clinics in the United States. The study was initiated at the first site in September of 2012. Adult subjects seeking hair reduction in the axillae were considered for enrollment. Subjects were treated with the miraDry System MD4000 using the standard miraDry procedure in one or two treatment sessions 3 months apart.

Fifty-six subjects were enrolled in the study. The mean age was 33 years; 80% of the subjects were female and 88% were Caucasian. The majority of the subjects were of Fitzpatrick skin type I-IV. 23% (13/56) of the subjects completed only one treatment session; 5 of these 13 subjects declined a second session due to adverse events. The primary endpoint of this study was to show >30% reduction (baseline to 3 month, measured by hair counts) in >50% of subjects. There were 42 subjects assessable for this endpoint. The secondary endpoint was to show >30% reduction (comparing baseline to 12 months photos) to make a claim for permanent axillary hair reduction. Additional analyses used a blinded comparison of baseline to follow-up full-axilla photos by an independent physician reviewer to correctly identify which photo had more hair and score hair reduction at follow-up. Also, a subject assessment of overall satisfaction, odor rating and sweat ratings was determined at the follow-up visits. A summary of the results is presented in Table 2 below.

Table 2: Summary of Efficacy Results.

Efficacy measure	Follow-up visit time from the last treatment session			
	3 months	6 month	9 month	12 month
Hair count: % of subjects with >30% reduction [lower 95% CL]	**Primary:** 88.1% (37/42) [76.6%]	97.5% (39/40) [88.7%]	92.1% (35/38) [80.8%]	**Secondary:** 95.5% (42/44) [86.4%]
Hair count: Average reduction [std] Light hair subgroup (n)	66% [± 30%] 66% (n=12)	72% [± 29%]	75% [± 28%]	75% [± 27%] 72% (n=13)
Side-by-side axilla review: % of pairs having at least 26-50% reduction	74% (63/85)	78% (65/83)	78% (66/85)	89% (83/93)
Patient satisfaction with hair reduction: % of subjects rating “very satisfied” or “somewhat satisfied”	81% (38/47)	70% (31/44)	68% (30/44)	70% (33/47)
Odor self-assessment, Mean reduction 10pt scale	2.6 ± 3.0	2.8 ± 2.8	2.5 ± 2.8	2.4 ± 2.7
% of subjects with HDSS reduction to score of 1 or 2	92% (23/25)	96% (25/26)	96% (24/25)	89% (25/28)

Both the primary and secondary endpoints were met, since the percentage of patients with hair reduction of at least 30% was significantly higher than 50% at all follow-up timepoints.

All subjects experienced at least one (1) treatment-related adverse event (AE), 99% (324/326) of all AE’s were rated as mild in severity. Many subjects experienced the expected mild transient post-treatment effects; the most common were localized edema (55%), tingling or numbness in the treatment area (30%), vacuum acquisition marks (29%), bumps or lumps under the skin (29%) or discomfort or tenderness in the treatment area (26%). Other rarer treatment effects affecting more than the treatment area were noted in 18% of subjects (10/56), 75% of which were rated as mild. These included numbness or tingling in the arms (n=6 events); more extensive swelling in the adjacent area (e.g. arms) (n=4 events); and bruising outside the treatment area (n=2 events). One patient experienced unilateral ulnar neuropathy that was improving but not completely resolved at study exit. The types, rates and severity of the reported AE’s are substantially equivalent to those from the predicate device (MD4000-MC with the hyperhidrosis indication, K131162).

The modification to the Indications for Use statement has not altered the fundamental technology of the miraDry System MD4000.

CONCLUSION

As described in this 510(k) Summary, Miramar Labs Inc. considers the miraDry System MD4000 to be substantially equivalent to the predicate device.