DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 31, 2016

Miramar Labs Incorporated
Ms. Kathy O'Shaughnessy
Consultant, Regulatory Affairs
2790 Walsh Avenue
Santa Clara, California 95051

Re: K160141
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: OUB, NEY, MWY
Dated: September 19, 2016
Received: September 20, 2016

Dear Ms. 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" (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,

Jennifer R. Stevenson -A

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)*
K160141

Device Name
miraDry System

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 for the treatment of primary axillary hyperhidrosis, the miraDry System MD4000 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.

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1. 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 MD4000 System
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/QA (Consulting)
Date prepared:	10/27/16

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 for the treatment of primary axillary hyperhidrosis, the miraDry System MD4000 may reduce underarm odor.

PREDICATE DEVICE

The miraDry MD4000 System (K150419).

DEVICE DESCRIPTION

The miraDry MD4000 that is the subject of this 510(k) is identical to the device described and cleared in K150419, except for the proposed labeling changes that resulted in this 510(k) submission.

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: 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 K150419 and prior submissions, the miraDry MD4000 System 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 and the 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 has a sterile, disposable barrier, the miraDry bioTip, which contacts the patient.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The miraDry MD4000 System described and cleared in 510(k) number K150419 serves as the predicate device for this premarket notification. The miraDry MD4000 System that is the subject of this 510(k) has the same intended use and technological characteristics as the device described and cleared in 510(k) number K150419. Furthermore, there have been no changes in design, material, chemical composition, energy source, or manufacturing process since FDA's clearance of K150419.

Substantial Equivalence Comparison Table

Characteristics	Predicate Device miraDry MD4000 K150419	Subject Device miraDry MD4000
Device Class	II	II
Energy Type	Microwave	Microwave
Mode of Action	generation of localized heat	generation of localized heat
Product Code	NEY, OUB, MWY	NEY, OUB, MWY
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.	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 for the treatment of primary axillary hyperhidrosis, the miraDry System MD4000 may reduce underarm odor.
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
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 MD4000 System, cleared under K150419).

CLINICAL TESTING

In support of this 510(k), a prospective, split-patient, randomized, single center trial was conducted. Forty adult subjects with high underarm odor were enrolled. Subjects were treated in one underarm (randomly selected) with the miraDry MD4000 System using the standard miraDry procedure, which at the time of the study was two treatment sessions 3 months apart. The other underarm was untreated and served as the control.

The odor assessments were conducted by four blinded, trained odor assessors, where each assessor gave a score to each underarm between 0 (no malodor) and 10 (extremely strong malodor). Scores for each underarm were obtained by averaging the scores from the four judges. Patients also self-reported their odor scores and rated their satisfaction with the procedure. The mean subject age was 49 years; 63% of the subjects were female and 57% were African American, with the remainder Caucasian.

The study design and results are summarized in the table below.

Study Design	Prospective, split-patient, randomized, single center trial
Sample Size	40 patients – one underarm treated, one underarm untreated
Odor Assessment Method	Panel of 4 blinded, trained odor assessors; each underarm rated on a scale of 0 (none, no malodor) to 10 (extremely strong malodor) and averaged
Principal Eligibility Criteria	• Score of at least 5 in each underarm; less than a 2 point difference between underarms • Willing to comply with washout period instructions prior to each odor assessment • Willing to receive the miraDry treatments and available for the follow-up period
Follow-ups	1 month, 3 months and 6 months after last treatment
Endpoints	Primary: Percentage of the subjects that scored at least a 2 point lower odor score in the treated underarm compared to the untreated underarm (responders) when assessed1 month after treatment Secondary: • Statistically significant difference in % of subjects with at least a 2 point drop in underarm odor score in the treated underarm compared to the untreated underarm at 3 and 6 months. • Average difference in odor in the treated underarm compared to the untreated underarm at all follow-up visits. • Patient-rated satisfaction scores on odor specific questions, as measured at the follow-up visits that are 1, 3 and 6 months post final treatment

Effectiveness results

The results for the responder analysis are shown in the table below for the subjects that attended the study visits.

Table 1: Percentage of subjects with at least 2 point lower odor score in the treated underarm compared to the untreated underarm

	# of Evaluable subjects	Percentage of subjects with at least 2 point lower odor score in the treated underarm compared to the untreated underarm 1 month after treatment.
1 month after treatment	35	23/35 (66%)*
3 months after treatment	36	14/36 (39%)
6 months after treatment	36	13/36 (36%)

*p=0.09, indicating the proportion of subjects experiencing a 2 point difference (between the treated and untreated underarm) was not significantly greater than 50%.

The primary endpoint and a secondary endpoint were not met, since the percentage of patients with at least a 2 point lower score on the treated underarm compared to the untreated underarm was not statistically significant at the three time points. However, the treated underarm was scored as having lower odor at all time points.

Table 2: Average difference in odor in the treated underarm compared to the untreated underarm at all follow-up visits.

	Average difference in odor between the treated and untreated underarm (± 95%CI)	P value
1 month	2.84 (±0.73)	<0.0001
3 months	1.27 (±0.74)	0.0005
6 months	1.56 (±0.56)	<0.0001

The treated underarm was rated by judges as having lower odor scores than the untreated underarm at every time point. Therefore, although the primary endpoint of statistically significant responder rate of 2 point reduction in odor was not met, the study data demonstrate some reduction of underarm odor when used for the treatment of primary axillary hyperhidrosis.

	Finally, subjects were asked about their general satisfaction and if they would be willing to receive treatment for free on the untreated arm. In response to the general satisfaction question, 29/35 or 83% reported being at least somewhat satisfied. However, only 15/36 or 42% responded that they would like undergo treatment of the untreated underarm at no cost.
Safety results	About half the treated subjects reported expected post-treatment effects such as localized edema and discomfort (Grade 0 events). One patient reported a mild infection that cleared in 10 days; another patient reported pain likely due to an infection after the optional biopsy; this cleared in 12 days.
Histo-pathology results	An optional component of the study was to obtain small biopsies from each of the treated and untreated (control) underarms after the final follow-up visit (6 months post-treatment). A blinded histopathologist review of the available pairs with adequate samples found: (1) In 7/10 cases the control sample had more apocrine glands (2) In 8/10 cases the treated sample had a higher degree of fibrosis.

CONCLUSION

The changes in Indications for Use do not pose any new questions of safety or efficacy. As demonstrated through clinical testing, the subject device miraDry MD4000 System's safety and effectiveness are substantially equivalent to those of the legally marketed predicate device (K150419).