K103014

510(k) Summary

JAN 2 8 2011

General Information

Trade Name	miraDry System
Classification	21CFR 878.4400, Electrosurgical cutting and coagulation device and accessories Class II (special controls)
Product Code	NEY
Submitter	Miramar Labs, Inc. 445 Indio Way Sunnyvale, CA 94085 USA Tel: 408-940-8700 Fax: 408-940-8795
Contact	Kathy O'Shaughnessy, PhD VP, Clinical and Regulatory Affairs
Date prepared:	January 20, 2011

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 treating hyperhidrosis related to other body areas or generalized hyperhidrosis.

Predicate Device

K082819	Miramar Labs' DTS G2 System

Device Description

The miraDry System is a microwave device designed to heat tissue located at the dermal- hypodermal interface where the sweat glands reside using a surface contact applicator. The miraDry System consists of: the DTS3000

Console; the miraDry Handpiece; and a disposable, sterile miraDry bioTip that snaps onto the Handpiece to provide a sterile protective cover.

The DTS3000 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 console connector that supplies the energy and cooling to the Handpiece. The distal end has a sterile, disposable barrier, the miraDry bioTip, that contacts the patient.

Materials

All materials used in the manufacture of the miraDry System are suitable for this use and have been used in numerous previously cleared products. Patient-contacting materials have been demonstrated to be biocompatible.

Performance Testing

Product and animal testing was conducted to ensure conformance to product specifications, and equivalence to the predicate device. In particular, animal testing demonstrated that thermal zones created with the predicate device were similar to those created with the miraDry System.

The miraDry System has been shown to conform to the applicable requirements of the following:

- IEC 60601-1: (1988 + A1:1991 + A2:1995) Medical Electrical Equipment Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: (2001+A1:2004) Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility
- IEC60601-1-4:2000. Medical Electrical Equipment Part 1-4 General requirement for safety - Collateral Standard: Programmable electrical medical systems
- IEC60601-1-6:2004. Medical electrical equipment Part 1-6: General requirements for safety – Collateral Standard: Usability
- IEC 60601-2-2:2006. Medical electrical equipment Part 2-2: Particular requirements for the safety of High Frequency Surgical Equipment
- IEC 60601-2-6:1984. Medical electrical equipment Part 2: Particular requirements for the safety of microwave therapy equipment.

Clinical testing showed that the device provides a safe and effective means to treat axillary hyperhidrosis. A randomized, blinded study with 120 subjects with primary axillary hyperhidrosis was conducted. The study primary endpoint was met, which demonstrated a statistically significant difference in sweat

reduction efficacy between the treated subjects (n=81) and the subjects that received a sham treatment (n=39). Adverse events were generally mild in severity and all but one (persistent hyperhidrosis on the face) resolved.

Summary of Substantial Equivalence

The miraDry System is substantially equivalent to the predicate product for the following reasons:

1. The miraDry System has the same intended use as the legally marketed DTS G2 System, i.e., a localized and controlled heating of soft tissue.
2. The indication for use for the miraDry System is a specific indications for use within the "functional" indications for use for the DTS G2 System that were cleared by FDA, i.e., "The DTS G2 System is indicated for use for coagulation of soft tissue".
3. The materials used in the miraDry System, the device's methods of manufacturing and overall function are the same as the FDA cleared DTS G2 System.
4. While the miraDry System has the same intended use and basic technological characteristics as the predicate, the specificity of the miraDry System's indications for use prompted Miramar Labs to conduct a clinical study to ensure that the performance specifications of the device met user needs. On the basis of direct comparison with the predicate device and the results of preclinical and clinical testing, the miraDry System has been demonstrated to be substantially equivalent to the legally marketed DTS G2 System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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JAN 28 2011

Re: K103014
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
Dated: December 10, 2010
Received: December 13, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

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

Enclosure

K103014

1 Indications for Use

510(k) Number (if known):

Device Name:	miraDry System
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.

X
Prescription Use
(Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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