K082819

510(k) Summary

General Information

Classification	Class II
Trade Name	DTS G2 System
Submitter	Miramar Labs, Inc. 199 Jefferson Drive Menlo Park, CA 94025 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Kathy O'Shaughnessy, PhD VP, Clinical and Regulatory Affairs

MAR 20 2009

Intended Use

The DTS G2 System is indicated for use for coagulation of soft tissue.

Predicate Devices

K072870 Foundry Newco X Microwave Tissue Coagulation System

Device Description

The DTS G2 System is designed to interact using a surface contact applicator. The system consists of an applicator; external microwave generator with integrated vacuum pump; and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, integrated vacuum pump, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator. The distal end has a sterile, disposable applicator head that contacts the patient.

Materials

All materials used in the manufacture of the DTS G2 System are suitable for this use and have been used in numerous previously cleared products.

Testing

Product and animal testing was conducted to evaluate conformance to product specification and equivalence to predicate devices.

The results showed the system met specification.

Summary of Substantial Equivalence

The DTS G2 System is equivalent to the predicate product. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Miramar Labs, Inc.
% Kathy O'Shaughnessy, PhD
VP, Clinical and Regulatory Affairs
199 Jefferson Drive
Menlo Park, California 94025

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Re: K082819
Trade/Device Name: DTS G2 System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: February 27, 2009
Received: March 2, 2009

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.

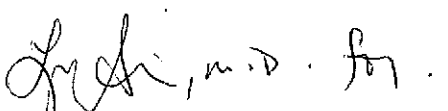
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082819

Indications for Use

510(k) Number (if known):	K082819
Device Name:	DTS G2 System
Indications for Use:	The DTS G2 System is indicated for use for coagulation of soft tissue.

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 P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082819