**510(k) Summary**

APR 0 9 2003

K023311

General Information

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|---|---|
| Classification | Class II |
| Trade Name | Loop™ Microwave Ablation Probe |
| Submitter | Vivant Medical, Inc.<br>1916-A Old Middlefield Way<br>Mountain View, CA 94043<br><br>650-694-2900 |
| Contact | Steven Kim<br>Director of Research and Development |

Intended Use

The Loop™ Microwave Ablation Probe is intended for coagulation of soft tissue. Not for use in cardiac procedures.

Predicate Devices

| | |
|---|---|
| VivaWave™ Microwave System – Vivant Medical, Inc. | K011676 |
| Bovie Hand Control – Sybron Corp. | K790187 |

Device Description

The device consists of a pre-shaped curved microwave antenna which is contained within a delivery cannula. The electrode is attached to a handle mechanism that deploys the antenna into the targeted tissue. The electrode comes with a connector that can be attached to a standard RF electrosurgical generator to assist in deployment of the curved microwave antenna into tissue. Once the curved antenna is fully deployed, the RF connector can be removed and the remaining microwave cable is connected to the Vivant VivaWave™ Microwave Generator. The microwave energy is then transmitted to the curved antenna which heats the tissue within and around the antenna.

Materials

All patient contact materials used in the manufacture of the Loop™ Microwave Ablation Probe are suitable for this use and have been used in numerous previously cleared products.

Summary of Substantial Equivalence

The Loop™ Microwave Ablation Probe is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Vivant Medical believes the Loop™ Microwave Ablation Probe is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 9 2003

Mr. Steven Kim
Director of Research and Development
Vivant Medical, Inc.
1916-A Old Middlefield Way
Mountain View, California 94043

Re: K023311
Trade/Device Name: Loop™ Microwave Ablation Probe
Regulation Number: 21 CFR 878.4400
Regulation Names: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: II
Product Codes: GEI
Dated: January 9, 2003
Received: January 10, 2003

Dear Mr. Kim:

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 Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): ~~This application~~ K023311

Device Name: Loop™ Microwave Ablation Probe

Indications for Use: The Loop™ Microwave Ablation Probe is intended for coagulation of soft tissue. Not for use in cardiac procedures.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023311