K020711

JUN 0 3 2002

510(k) Safety and Effectiveness Summary

Applicant: Wallach Surgical Devices, Inc,
235 Edison Road
Orange, CT 06477
Registration: 1219739
Contact: Michael Malis
Phone: 203-799-2000
Fax: 203-799-2002

Trade Name: Wallach LOOP Electrode

Devices Generic Name: Electrosurgical Electrode

Classification Name: Electrode, Electrosurgical

Classification: Currently classified as a Class II, under Product Code 79 GEI, Regulation Number 878.4400, 21 CFR.

Predicate Devices to which we are claiming substantial equivalence:

1 Unimed 'Surgi-Link Eletrosurgical Electrode', K944433,
2 Megadyne 'Electrosurgical Electrode, K932102,

Product Description:

The **Wallach LOOP Electrode** is a Sterile, Disposable, Single Use Electrode. Used in conjunction with an ESU (electrosurtical unit or generator) to CUT or COAG during an electorsurgical procedure.

Indications for Use:

Used to excise target tissue, perform biopsies and control bleeding through a standard Monopolar Electrosurgical Generator.

Safety and Performance:

Substantial equivalence for this device is based on design, operation, intended use, materials, and performance claims. Testing that was performed on the Wallach LOOP Electrodes indicates that the devices are substantially equivalent in the performance and design of operation.

Hazard analysis evaluations performed on the Wallach LOOP Electrodes indicated that there were no new hazards presented with the use of the Wallach LOOP Electrodes as compared to the predicated devices.

Comparison Chart:

Feature:	Wallach Surgical Devices, Inc. Wallach LOOP Electrodes **K**_____ (pending) Class II, Product Code: GEI Regulation #: 878.4400	UNIMED Surgical Products, Inc. Surgi-Link Electrosurgcial Electrode **K944433** Class II, Product Code: GEI Regulation #: 878.4400	Megadyne Medical Products, Inc. Electrosurgical Electrodes **K932102** Class II, Product Code: GEI Regulation #: 878.4400
Intended Use:	With an ESU for CUT and COAG	Equivalent	Equivalent
Sterile, Disposable Single Use	Yes	Yes	Yes
Design:	Tungsten Wire Curved Loop Square Loop Stainless Steel Ball	Equivalent	Equivalent
Material	Tungsten Wire Stainless Steel Shaft Stainless Steel Ball Polyolefin Insulation	Equivalent	Equivalent
Conforms with ANSI/AMMI HF18-1993	Yes	Unknown	Unknown
Sizes:	3mm Ball 5mm Ball 5mm Ball 6cm Shaft 10mmX7mm Loop 10mmX10mm Loop 15mmX5mm Loop 15mmX8mm Loop 20mmX8mm Loop 20mmX10mm Loop 20mmX15mm Loop 10mmX8mm Square 10mmX10mm Square 0.8mm Needle, 6" Shaft	Similar	Similar

Conclusion:

Based on the indications for use, technological characteristics and comparison to currently marketed devices, the Wallach LOOP Electrode has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2002

Mr. Michael Malis
General Manager
Wallach Surgical Devices, Inc.
235 Edison Road
Orange, CT 06477

Re: K020711
Trade/Device Name: Wallach LOOP Electrode
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 4, 2002
Received: March 5, 2002

Dear Mr. Malis:

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.

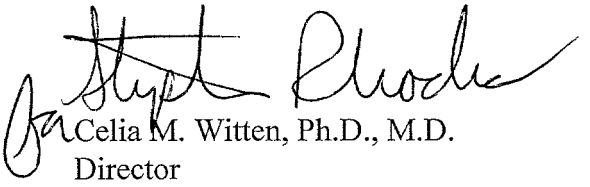
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,



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

510(k) Number (if known): 020711

Device Name: Wallach LOOP Electrode

Indications For Use:

Used to excise target tissue, perform biopsies and control bleeding through a standard Monopolar Electrosurgical Generator.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K020711

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