AUG 12 1999

K991669

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: **PMS750 Fingerswitch**

Device Generic Name: Fingerswitch or Handswitch Pencil.

Classification Name: Device, Electrosurgical, Cutting & Coagulation & Accessories.

Classification: Currently the device classification is **Class II**, under Product Code 79 **GEI**, Regulation Number 878.4400, 21 CFR.

Predicate Devices to which we are claiming substantial equivalence:

1. Aaron Electrosurgical Handcontrol Pencil, Reusable, K983761, 12/30/98.
2. Medtrex's Encore™ Electrosurgical Pencil (35001-), Reusable, K970039, 02/26/97.
3. E & M Engineering's Reusable Hand Controlled ESP, Reusable, K936075, 06/06/94.
4. Conmed's Tech-Switch Electrosurgical Pencil, Reusable, K932518, 10/12/93.

Product Description:

The **PMS750 Fingerswitch** Pencil is a non-sterile, limited reusable electrosurgical handcontrol pencil. It utilizes an insert-molded body that houses a printed circuit board; depression of the yellow button will activate the CUT circuit and depression of the blue button will activate the COAG circuit. It is an accessory to an ESU (electrosurgical unit or generator).

Indications for Use:

The **PMS750 Fingerswitch** is intended to be used in general electrosurgical applications for cutting and coagulating during surgical procedures. It is provided non-sterile and is intended for limited reuse.

Safety and Performance:

Substantial equivalence for this device is based on design, operation, intended use, materials, components and performance claims. Testing that was performed on the **PMS750 Fingerswitch** indicates that the devices are substantially equivalent in their performance and design of operation.

Hazard analysis evaluations performed on the **PMS750 Fingerswitch** indicated that there were no new hazards presented with the use of the **PMS750 Fingerswitch** as compared to the predicate devices.

SUBSTANTIAL EQUIVALENCE CHART

	Wallach Surgical **PMS750 Fingerswitch**, Reusable K 991669 [this 510(k)]	Aaron Electrosurgical Handcontrol Pencil, Reusable, K983761, 12/30/98.	Medtrex Encore™ Electrosurgical Pencil (35001-), Reusable, K970039, 02/26/97.	E & M Engineering Reusable, Hand Controlled ESP, K936075, 06/06/94	Conmed Tech-Switch Electrosurgical Pencil, Reusable, K932518, 10/12/93
Materials	polypropylene	similar	similar	similar	similar
Sterilization	autoclavable	equivalent	equivalent	equivalent	equivalent
Design	Encapsulated circuit board	equivalent	equivalent	equivalent	equivalent
Intended Use	With an ESU for CUT & COAG	equivalent	equivalent	equivalent	equivalent
Where Used	By a Physician	equivalent	equivalent	equivalent	equivalent

Conclusion:

Based on the indications for use, technological characteristics and comparison to currently marketed devices, the **PMS750 Fingerswitch** 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

AUG 12 1999

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

Re: K991669
Trade Name: PMS 750 Fingerswitch
Regulatory Class: II
Product Code: GEI
Dated: May 11, 1999
Received: May 14, 1999

Dear Mr. Malis:

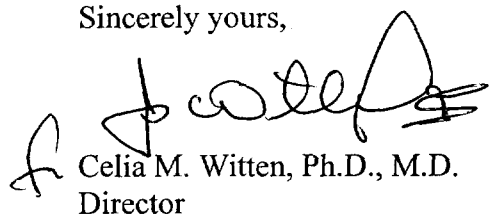
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K991669

Device Name: PMS750 Fingerswitch Pencil

Indications For Use:

The PMS750 Reusable (Autoclavable) Fingerswitch Pencil is intended to be used in general electrosurgical applications for cutting and coagulating during electrosurgical procedures. It is provided non-sterile and is intended to be autoclavable for 100+ cycles.

(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 Devices
510(k) Number K991669

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)