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's Ultimate Reusable, Plastic Vaginal Speculum**

Device Generic Name: Speculum.

Classification Name: Speculum, Vaginal, Nonmetal.

Classification: Currently the device classification is **Class II**, under Product Code 85HIB, Regulation Number 884.4530, 21 CFR.

Predicate Devices to which we are claiming substantial equivalence:

Adept-Med's Gravespec Reusable Nonmetal, Vaginal Speculum, K935636, 03/25/94.
CooperSurgical's Prima Series, Vaginal LEEP Plastic Reusable Specula, K951898, 12/11/95.

Product Description:

The Ultimate Reusable, Plastic Vaginal Speculum is a device used to expose the interior of the vagina during general gynecologic and electrosurgical procedures. The non-conductive, specialized plastic stops dangerous grounding of the electrical current that a metal would not. The stainless steel metal parts will not rust and are away from the operating area. The three main parts are injection molded from a plastic called ULTEM, a General Electric Company product used for many years in the manufacturing of medical devices, where high temperature and chemical interaction is a concern. The speculum has been autoclaved and cold soak sterilized for many hours to be sure of its usability after repeated cycles and there is no coating to breakdown, crack, chip, or peel. The color is pink to stop light reflection (as opposed to white) and still light enough to show any surface damage that might happen in use. The surfaces are polished and all sharp edges are removed for the protection of the patient.

Indications for Use:

The Wallach Ultimate Reusable, Plastic Vaginal Speculum is intended to be used for general gynecologic and electrosurgical procedures and is inserted into the vagina to expose the cervix. It is supplied non-sterile and is intended to be autoclavable for 100+ cycles.

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 **Ultimate Reusable, Plastic Vaginal Speculum** indicates that the devices are substantially equivalent in their performance and design of operation.

Hazard analysis evaluations performed on the **Ultimate Reusable, Plastic Vaginal Speculum** indicated that there were no new hazards presented with the use of the **Ultimate Reusable, Plastic Vaginal Speculum** as compared to the predicate device.

SUBSTANTIAL EQUIVALENCE CHART

	Wallach'Surgical's Ultimate Reusable, Plastic Vaginal Speculum K_____ [this 510(k)]	**CooperSurgical's Prima Series Vaginal LEEP Reusable Plastic Speculum K951898 12/11/95.**	**Adept-Med Int'l, Inc. Gravespec® Reusable, Plastic Speculum K935636 3/25/94**
Materials	Ultem Plastic.	Equivalent	Similar
Sterilization	Autoclavable / Reusable.	Equivalent	Similar
Design	1. Plastic Injection Molded. 2. Non-conductive. 3. No coating to breakdown, crack, chip, or peel.	1. Equivalent 2. Equivalent 3. Equivalent	1. Equivalent 2. Equivalent 3. Equivalent
Intended Use	To assist in electrosurgical procedures to expose the interior of the vagina.	Equivalent	Equivalent
Where Used	By a Physician.	Equivalent	Equivalent

Conclusion:

Based on the indications for use, technological characteristics and comparison to a currently marketed device, the **Ultimate Reusable, Plastic Vaginal Speculum** 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

SEP 29 1999

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

Re: K992736
Wallach Ultimate Reusable, Plastic
Vaginal Speculum
Dated: August 10, 1999
Received: August 13, 1999
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HIB

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 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). 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5-1 9/15/99

Wallach Surgical Devices, Inc.
SECTION 5

510(k) Number (if known): K992736

Device Name: **Wallach Ultimate Reusable, Plastic Speculum**

Indications For Use:

The Wallach Ultimate Reusable, Plastic Vaginal Speculum is intended to be used for general gynecologic and electrosurgical procedures. This product is inserted into the vagina to expose the cervix.

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

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)

Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992736