WALLACH
Surgical Devices, Inc.
235 Edison Road
Orange, CT 06477
(203) 799-2000
Fax: (203) 799-2002

JUL 12 2002

510(k) Summary/Statement Certification

Re: K 021224 **Device Name: "Wallach Endocervical Block Needle"**

Check Only One:

√ 1. **510(k) Summary.** Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

2. **510(k) Statement, I Certify that, in my capacity as GENERAL MANAGER, of WALLACH SURGICAL DEVICES, INC.**

I will make available all information included in this premarket notification of safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

M. Malis — Michael Malis
(Signature) (Typed or Printed name)

4/15/02
(Dated)

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 Endocervical Block Needle
Devices Generic Name:	Endocervical Block Needle
Classification Name:	Set, Anesthesia, Parcervical, and Needle, Hypodermic, Single Lumen
Classification:	Currently classified as a Class II, under Product Code 85 HEE Regulation Number 884.5100 and Product Code 80 FMI Regulation Number 880.5570 per 21 CFR.

Predicate Devices to which we are claiming substantial equivalence:

1 Coopersurgical 'Potocky Needle', K910252
2. Avid Medical 'Avid-Nit Cervical Regional Anesthesia Needle', K000117
3. Terumo Medical 'Terumo 30 Gauge Hypodermic Needle', K012646
4. Nipro Medical Crop 'Nipro Hypodermic Needel', K013293

Product Description:

The **Wallach Endocervical Block Needle** is a Sterile, Disposable, Single Use device. The needle is 27ga., 3 ½" long. It is used for uterine anesthesia prior to Ob/Gyn procedures. It consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (Luer lock) designed to mate with a male connector (Nozzle) of a piston syringe or an intra-vascular administration set. Over 3 ¼" of its proximal end a 21 gauge metal tube is added to strengthen the shaft.

Indications for Use:

It is designed for injection of solutions (such as 2% lidocaine with or without 1:100,000 epinephrine) into the cervix. The application includes local anesthetics such as electro-excision, electro-fulguration, CO2 laser excision and vaporization, and when required, endocervical curettage and cervical biopsies.

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 Endocervical Block Needle indicates that the devices are substantially equivalent in the performance and design of operation.

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

Comparison Chart:

Feature:	Wallach Surgical Devices, Inc. 'Wallach Endocervical Block Needle' **K**_____ (pending) Class II, Product Code HEE Regulation # 884.5100 and Product Code FMI Regulation # 880.5570	Coopersurgical 'Potocky Needle' **K910252** Class II, Product Code: HEE Regulation # 884.5100	Avid Medical Inc. 'Avid-Nit Cervial Regional Anesthesia Needle' **K000117** Class II, Product Code: HEE Regulation # 884.5100	Terumo Medical Corp. 'Terumo 30 Ga. Hypodermic Needle' **K 012646** Class II, Product Code: FMI Regulation # 880.5570	Nipro Medical Corp. 'Nipro Hypodermic Needle' **K013293** Class II, Product Code: FMI Regulation # 800.5570
Intended Use:	For injection of solutions (such 2% lidocaine with or without 1:100,000 epinephine) into the cervix. The application includes local anesthetics such as eletro-excision, elecro-fulguration, CO2 laser excision and vaporization, and when required, endocervical curettage and cervical biopsies	Equivalent	Equivalent	Equivalent	Equivalent
Sterile, Disposable Single Use	Yes	Yes	Yes	Yes	Yes
Design:	The needle is 27ga., 3 ½" long. It is used for uterine anesthesia prior to Ob/Gyn procedures. It consists of a metal tube that is sharpened at one end and at the other	Equivalent	Equivalent	Similar	Similar

	end joined to a female connector (Luer lock) designed to mate with a male connector (Nozzle) of a piston syringe or an intra-vascular administration set. Over 3 ¼" of its proximal end a 21 gauge metal tube is added to strengthen the shaft.				
Material	Stainless Steal Tubing Plastic Hub	Equivalent	Equivalent	Equivalent	Equivalent

Conclusion:

Based on the indications for use, technological characteristics and comparison to currently marketed devices, the Wallach Encodervical Block Needle 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

JUL 12 2002

Mr. Michael Malis
General Manager of Operations
WALLACH Surgical Devices, Inc.
235 Edison Road
ORANGE CT 06477

Re: K021224
Trade/Device Name: Endocervical Block Needle
Regulation Number: 21 CFR 884.5100
Regulation Name: Obstetric anesthesia set
Regulatory Class: II
Product Code: 85 HEE
Dated: April 15, 2002
Received: April 17, 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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021224

Device Name: Wallach Endocervical Block Needle

Indications For Use:

This needle is designed for injection of solutions (such as 2% lidocaine with or without 1:100,000 epinephrine) into the cervix. The application includes local anesthetics such as electro-excision, electro-fulguration, CO2 laser excision, and vaporization, and when required, endocervical curettage and cervical biopsies.

(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)

David A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021224