K012859
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OCT 2 6 2001

SOL WEISS, M.D., INC.
7012 RESEDA BOULEVARD, SUITE A
RESEDA, CALIFORNIA 91335
TELEPHONE (818)346-1515
FAX (818)705-5300

510(k) Summary

10.

Date	August 22, 2001
Manufacturer:	Not applicable at time of submission. Established Registration will be submitted upon determination of manufacturer
Owner:	Sol Weiss, M.D. 7012 Reseda Boulevard Suite A Reseda, California 91335
Contact Person:	Sol Weiss, M.D.
Device Trade Name:	Nu-Spec D
Common Name:	Vaginal Speculum disposable
Classification Name:	Speculum
Regulatory Reference:	884.4530(17)

Description (Exhibit F_1, F_2 and G):

- The device is made of injected molded parts
- The device assembly includes a window trap for pins to snap together
- The instrument has levels in the windows to lock positions as desired by the expanding vertical blades
- The lateral blade protectors act to prevent lateral walls from cascading into view area.
- Lateral protector blades are same thickness of vertical blades thus act as rigid barriers
- Lateral protector blades conform with the design of vertical blade that provide rigid conforming structures that allows smooth unchanged entrance
- The device once snapped together do not require any further assembly

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510(k) Summary

- The device is for single use only

Intended use:

- The intended use is to expose the interior of the vagina
- The intended use is to maintain a clear and protected area of view

Physical / Technical Comparison:

- Have the same intended use
- Manufactured through injection molding
- Made with same materials
- Maintain same rigidity for vaginal viewing
- Both have clear plastic for viewing
- Share the same release mechanisms
- Share the same opening / closing and locking mechanisms in use
- Both have same configurations for handling and gripping

Differences:

- The lateral wall protectors keep viewing clear
- Lateral wall protectors afford less chances of injuring walls of vagina during procedures
- Do not alter the utilization of the instrument while affording safety and effectiveness

Performance Summary:

- Constructurally equivalent to the Cooper Speculum which has already been subjected to millions of applications

The Nu-Spec D complies with all acceptance criteria listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Sol Weiss, M.D.
Sol Weiss, M.D., Inc.
7012 Reseda Boulevard
Suite A
RESEDA CA 91335

Re: K012859
Trade/Device Name: Nu-Spec D™ Vaginal Speculum
or WEISS SPEC-D
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized
manual instrument
Regulatory Class: II
Product Code: 85 HIB
Dated: August 22, 2001
Received: August 24, 2001

Dear Dr. Weiss:

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.

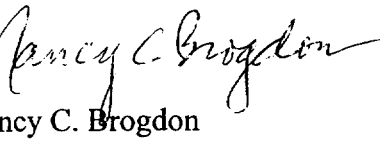
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012859

Device Name: Nu-Spec-D; alternative name is Weiss Spec-D

Indications for use:

This device is to be used for exposing the interior of the vagina.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012859

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

(Optional Format 1-2-96)