

DEC 17 1997

**Summary of Safety and Effectiveness**

This summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92 and was prepared November 25, 1997.

**Submitter:** UroMetrics Inc.  
445 Etna Street  
Suite 56  
St. Paul, MN. 55106  
612-774-1552

**Contact Person:** Philip A. Messina  
President, COO

**Common Name:** Bi-directional Vascular Doppler with Spectral Analysis

**Proprietary Name:** Knoll/MIDUS

**Classification Name:** Ultrasonic transcutaneous blood flowmeter (w/wo calibration),  
21 CFR 8970.2100

**Classification:** Class II

**Predicate Device:** The Knoll/MIDUS is substantially equivalent to the SPECS USA, Inc. Stenodoc/EPC bi-directional vascular Doppler with spectral analysis (K946349).

**Description:** The UroMetrics Knoll/MIDUS System is an office based Doppler ultrasound system designed to measure blood velocity in the penile cavernosal arteries.

The system consists of a portable or desktop IBM compatible personal computer containing a proprietary circuit board and transducers. Blood velocity is determined by detecting the Doppler shifts of an 8 MHz ultrasound signal. Proprietary software converts this data into a useable waveform display, which is shown on the computer video display.

**Intended Use:** Measurement of penile cavernosal artery velocities. Not intended for fetal use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 17 1997

Phillip A. Messina  
President & COO  
UroMetrics, Inc.  
445 Etna Street, Suite 56  
Saint Paul, MN 55106

Re: K971790  
Knoll/MIDUS™ System (with  
SureAngle™ probes and  
Gold Guard™ cradle)  
Dated: December 5, 1997  
Received: December 8, 1997  
Regulatory Class: II  
21 CFR 892.1550/Procode: 90 IYN  
21 CFR 870.2100/Procode: 74 DPW

Dear Mr. Messina:

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. 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 registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Knoll/MIDUS™ System, as described in your premarket notification:

Transducer Model Number

TD1 (8MHz, CW Doppler)

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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

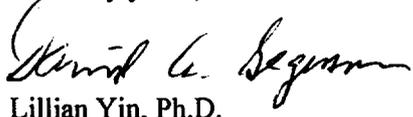
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo Perez at (301) 594-1212.

Sincerely yours,

*for*   
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K971790

Device Name: Knoll/MIDUS Male Intracavernosal Doppler UltraSound Transducer Model TD1

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

mode of operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Petal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-luminal										
Peripheral Vascular							X			
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

Additional Comments: \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David L. Seymour  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K971790