K980687

MAY 22 1998

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

1) Submitter's Name / Contact Person: Paul Schrader
Address: 3000 Minuteman Road, Andover Ma. 01810
Telephone Number: 978-659-2404
Date Summary was prepared: February 19, 1998

2) Trade Name: Sonos 5500 Ultrasound Imaging System
Common Name: Ultrasound Imaging System
Classification Pro Codes: 90 IYN / 90 IYO / 90 ITX

3) Identification of Predicate Device:

Predicate Device	SE Decision Date	510(k) Number
HP: Sonos 2500 Ultrasound System w/ Harmonic Imaging	4/22/97	K964309
Acuson: Sequoia Harmonic Imaging w/ contrast	12/23/97	K973767
ATL: High Definition Imaging (HDI) System	3/26/97	K961459

4) Description of the device or modification being submitted for premarket approval.

Functionality: No change. Design cleared with K964309 has the ability to perform harmonic imaging of tissue.

Scientific Concepts: Use of harmonic imaging reduces clutter in the image. Clutter exists in images of difficult to image patients. It therefore follows that reducing clutter if it exists will improve 2D/ B-mode image quality.

Significant Characteristics of the Modification: This submittal is being done solely for the purpose of allowing FDA to review claims of effectiveness.

Significant Safety Concerns: None. Harmonic Imaging of tissue is being done today with several systems already the market. They are manufactured and marketed by : HP, ATL, Acuson.

5) Statement of Intended Use: No change from existing platforms.

6) Predicate Device Comparison:
Diagnostic ultrasound imaging systems by their nature are designed to image tissue. There are also an increasing number of systems that have been designed to image contrast agents with harmonic imaging Comparisons made between HI of contrast agents and HI of tissue show that the existing HI design for contrast can also do HI of tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1998

Paul Schrader
Regulatory Affairs
Hewlett-Packard Company
Medical Products Group
3000 Minuteman Road
Andover, MA 01810

Re: K980687
Harmonic Tissue Imaging Option for the HP Sonos 5500 Ultrasound Imaging System
Dated: February 20, 1998
Received: February 23, 1998
Regulatory class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Schrader:

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 Act (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 Harmonic Tissue Imaging Option for the HP Sonos 5500 Ultrasound System, as described in your premarket notification:

Transducer Model Number

Model HP 21330A Phased Array

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.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

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 **Paul Gammell, Ph.D.** 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

Diagnostic Ultrasound Indications for Use Form
Fill out one form for each ultrasound system or transducer
Pg _1_ of Pg _1_

510(k) # (if known) : K980687
Device Name: Phased Array Transducer (21330A)

Indications for Use : Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows.

	Mode of Operation									
Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic	N/A	E	N/A	E	N/A	E	E	E	E	N/A
Fetal	N/A	E	E	E	E	E	E	E	E	N/A
Abdominal	N/A	E	E	E	E	E	E	E	E	N/A
Intra-Operative (Specify)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Intra-Operative Neurological	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pediatric	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Small Organ (Specify)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Neonatal Cephalic	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Adult Cephalic	N/A	E	E	E	E	E	E	E	E	N/A
Cardiac Adult	N/A	E	E	E	E	E	E	E	E	N
Cardiac Pediatric	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Trans-esophageal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Trans-rectal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Trans-vaginal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Intra-Luminal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Trans-urethral	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Peripheral Vessel	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Laproscopic	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

NA= Not applicable for this mode
N=New Indication P=Previously Cleared by FDA E= added under Appendix E

Combined modes are : B+M, B+M+Color (CVI), B+PW.

Other: Harmonic Imaging of tissue is a new indication (N) with this submittal
Harmonic Imaging of contrast agents was added under appendix E based on K964309 .

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Ofice of Device Evaluation (ODE)

David A. Seyer
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980687