

2/18/99

K990339

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Name: Ann Fay Michaels
Title Regulatory Engineer

Hewlett Packard Company
3000 Minuteman Road
Andover, MA 01810
Tel: (978)659-2980
Fax: (978)683-6337
Email: annmich@an.hp.com

This summary was prepared on December 09, 1998.

2. This premarket notification describes modifications to the indications for the Sonos 5500 M2424A system with the 21330A probe, and the addition of two probes. The common names for these devices are the Phased Array, Endocavity Probe and Intraoperative Probe for Sonos 5500 Ultrasound Imaging System. The classification names for these devices are: Ultrasonic Pulsed Doppler Imaging System, Ultrasonic Pulsed Echo imaging System and Diagnostic Ultrasound Transducer.

3. The modification involves expanded indications for use on the M2424A system to allow endocavity imaging using HP's endocavity transducer 21336A (K972348). Additionally, a new intraoperative transducer (21390A) that has new patient contact materials, is being added to the M2424A system. Also, the indications for the 21330A probe (K980687) are being expanded to include abdominal and adult cephalic applications with the harmonic tissue imaging option. Note: The HP M2424A platform has been previously cleared for harmonic tissue imaging for abdominal applications.

4. When connected to the Sonos 5500 system, all three transducers function in the same way as their predicate devices by allowing ultrasound imaging of the human anatomy.

5. The subject transducers have the same intended use as their predicates. The 21336A was cleared for endocavity applications on the M2410A (K972348). The 21390A has the same intended use as its predicate device 21380A cleared for intraoperative use on the M2424A system (K971116). The 21330A has the same intended use as Acuson Corporation's 3V2c

transducer on its Sequoia Ultrasound System (K973767) with respect to abdominal and adult cephalic applications.

6. The modifications to the M2424A system and its probes result in no new technological changes with respect to currently marketed predicate devices. As a new probe, the 21390A is similar to predicate devices in all respects except patient contact materials, and this 510(k) Notification includes biocompatibility test results that demonstrate biocompatibility of the new materials.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Hewlett-Packard Company
c/o Carole Stamp
TUV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K990339
Sonos 5500 Imaging System M2424 Version B.0
Regulatory Class: II
Product Code: 90 IYN 21 CFR 892.1550
 90 IYO 21 CFR 892.1560
 90 ITX 21 CFR 892.1570
Dated: February 2, 1999
Received: February 3, 1999

Dear Ms. Stamp:

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Sonos 5500 Imaging System M2424A Version B.0, as described in your premarket notification:

Transducer Model Number

Phased Array Model 21330A
Endocavity Model 21336A
Phased Array Model 21390A

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:

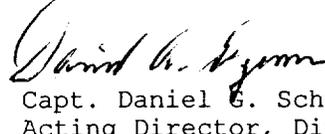
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Robert A. Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

for 

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

Enclosures

DUPLICATE

K990339

Diagnostic Ultrasound Indications for Use Form

510(k) Number:

Device Name: Sonos 5500 Ultrasound Imaging System (M2424A)

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

Clinical Application	MODE OF OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	NA	P	NA	P	NA	P	P	P	P	NA
Fetal	NA	P	P	P	P	P	P	P	P	NA
Abdominal	NA	P	P	P	P	P	P	P	P	P
Intraoperative (vascular/epicardial)	NA	P	P	P	P	P	P	P	P	NA
Intraoperative Neurological	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pediatric	NA	P	P	P	P	P	P	P	P	P
Small Organ (thyroid, scrotum and breast)	NA	P	P	P	P	P	P	P	P	P
Neonatal Cephalic	NA	P	P	P	P	P	P	P	P	P
Adult Cephalic	NA	P	P	P	P	P	P	P	P	N
Cardiac (Adult & Pediatric)	NA	P	P	P	P	P	P	P	P	P
Transesophageal	NA	P	P	P	P	P	P	P	P	P
Transrectal	NA	N	N	NA	N	N	NA	N	N	NA
Transvaginal	NA	N	N	NA	N	N	NA	N	N	NA
Transurethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intravascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vascular	NA	P	P	P	P	P	P	P	P	P
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Other (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

N = new indication; P = previously cleared by FDA; E = added under Appendix E.

Additional Comments: Combined modes are B+M, B+M+color (CV1), B+PW

Other: Harmonic Imaging of tissue was cleared under K980687. Harmonic Imaging of contrast agents was cleared under K964309.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K990339

Diagnostic Ultrasound Indications for Use Form

Device Name: Phased Array Transducer (21330A) on the M2424A

Intended Use: Diagnostic Ultrasound Imaging and Doppler Analysis of the human body as follows:

Clinical Application	MODE OF OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (tissue harmonics)
Ophthalmic	NA	E	NA	E	NA	E	E	E	E	NA
Fetal	NA	E	E	E	E	E	E	E	E	NA
Abdominal	NA	E	E	E	E	E	E	E	E	N
Intraoperative	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intraoperative Neurological	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pediatric	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Small Organ	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Neonatal Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Adult Cephalic	NA	E	E	E	E	E	E	E	E	N
Cardiac	NA	P	P	P	P	P	P	P	P	P
Transesophageal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transrectal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transvaginal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transurethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intravascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Other (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

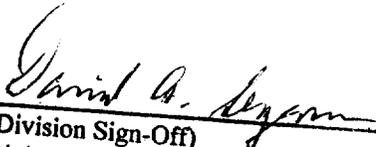
N = new indication; P = previously cleared by FDA; E = added under Appendix E.

Additional Comments: Other indications or modes: Combined modes are B+M, B+M+Color, and B+PW. Harmonic imaging of tissue was cleared under K980687. Harmonic imaging of contrast agents was cleared under K964309.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K990339

Diagnostic Ultrasound Indications for Use Form

510(k) Number: _____
 Device Name: Endocavity Transducer 21336A on the M2424A
 Intended Use: Diagnostic Ultrasound Imaging and Doppler Analysis of the human body as follows:

Clinical Application	MODE OF OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fetal	NA	E	E	E	NA	E	E	NA	E	NA
Abdominal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intraoperative (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intraoperative Neurological	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pediatric	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Small Organ (prostate)	NA	E	E	E	NA	E	E	NA	E	NA
Neonatal Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Adult Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Cardiac	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transesophageal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transrectal	NA	N	N	N	NA	N	N	NA	N	NA
Transvaginal	NA	N	N	N	NA	N	N	NA	N	NA
Transurethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intravascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Other (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

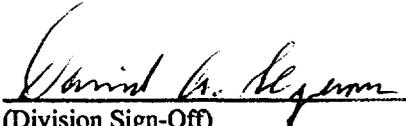
N = new indication; P = previously cleared by FDA; E = added under Appendix E.

Additional Comments: Combined modes are: B+M, and B+PW.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K990339

Diagnostic Ultrasound Indications for Use Form

Device Name: Phased Array Transducer (21390A) on the M2424A

Intended Use: Diagnostic Ultrasound Imaging and Doppler Analysis of the human body as follows:

Clinical Application	MODE OF OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fetal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Abdominal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intraoperative (vascular/epicardial)	NA	P	P	P	NA	P	P	P	P	NA
Intraoperative Neurological	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pediatric	NA	P	P	P	P	P	P	P	P	NA
Small Organ	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Neonatal Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Adult Cephalic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Cardiac	NA	P	P	P	P	P	P	P	P	NA
Transesophageal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transrectal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transvaginal	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transurethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Intravascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vascular	NA	P	P	P	P	P	P	P	P	NA
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Other (specify)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

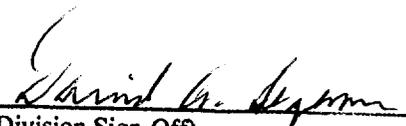
N = new indication; P = previously cleared by FDA; E = added under Appendix E.

Additional Comments: Other indications or modes: Combined modes are B+M, B+M+Color, and B+PW. "P" refers to 21380A (K971116).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
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 510(k) Number K990339