2/4/99

K990400

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:

Steve Singlar
Regulatory Approvals Engineer
Hewlett Packard Company
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This summary was prepared on January 12, 1999.

2. This premarket notification describes modifications to the ImagePoint M2410A system. It adds two new intended uses to the operating platform covering Musculo-Skeletal and Adult Cephalic (Transcranial Doppler) imaging. It adds harmonic imaging mode for the following applications: fetal, abdominal, pediatric, adult cephalic and cardiac. Hewlett-Packard considers Harmonic imaging to be a subset of 2D / B-mode imaging. This premarket notification also adds a transducer with new patient contact materials indicated for musculo-skeletal, vascular and small parts imaging. The classification names for these devices are: Diagnostic Ultrasound Transducer, Ultrasonic Pulsed Echo Imaging System and Ultrasonic Pulsed Doppler Imaging System.

3. The modification involves expanded intended uses to the M2410A system, as well as, the addition of a new transducer with new patient contact materials, to be known as the HP 21376A Transducer.

4. The ImagePoint system, with new platform modes, new indications for use, and new transducer, functions in the same way as its predicate devices, the M2410A (K954028), M2424A (K964309 and K980687) and the Acuson Aspen System, with L7 probe, (K973079) by allowing ultrasound imaging of the human anatomy.

5. The subject platform and transducer have the same functionality and intended uses as their predicates.

6. The M2410A platform and HP 21376A transducer on the M2410A are similar to the predicate devices in all respects except the transducer has new patient contact materials. This 510(k) Notification includes biocompatibility test results that demonstrate biocompatibility of the new materials.

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003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

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

Re: K990400
Linear Array Transducer HP 21376A
Regulatory class: II/21 CFR 892.1570
Procode: 90 ITX
Dated: February 5, 1999
Received: February 9, 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 Linear Array Transducer HP 21376A intended for use with the M2410A ImagePoint Ultrasound System, as described in your premarket notification.

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."

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

Sincerely yours,

for David G. Segmon

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

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Diagnostic Ultrasound Indications for Use Form

510(k) Number: _____
Device Name: Transducer HP 21376A on the M2410A
Intended Use: Diagnostic Ultrasound Imaging and Doppler 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	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 (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 Parts (small organ)	NA	N	N	N	NA	N	N	NA	N	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	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	N	N	N	NA	N	N	NA	N	NA
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	N	N	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	N	N	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+Color, B+Angio, B+PW, M+Color and , B+PW+Color (known as Triplex), are available in all HP 21376A applications as noted.
In the Small Parts application, the HP 21376A transducer supports imaging of the breast, thyroid and scrotum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Eleyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990400

Prescription Use (Per 21 CFR 801.109)

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007

Diagnostic Ultrasound Indications for Use Form

Device Name: M2410A ImagePoint Ultrasound System
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 (harmonic imaging)
Ophthalmic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fetal	NA	P	P	P	NA	P	P	NA	P	N
Abdominal	NA	P	P	P	NA	P	P	NA	P	N
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	P	P	P	P	P	P	NA	P	N
Small Parts [1] (small organ)	NA	P	P	P	NA	P	P	NA	P	NA
Neonatal Cephalic	NA	P	P	P	NA	P	P	NA	P	NA
Adult Cephalic	NA	N	N	N	NA	N	N	NA	N	N
Cardiac	NA	P	P	P	P	P	P	NA	P	N
Transesophageal	NA	P	P	P	P	P	P	NA	P	NA
Transrectal	NA	P	P	P	NA	P	P	NA	P	NA
Transurethral	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transvaginal	NA	P	P	P	NA	P	P	NA	P	NA
Intravascular	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Peripheral Vascular	NA	P	P	P	NA	P	P	NA	P	NA
Laparoscopic	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Conventional	NA	N	N	NA	NA	NA	NA	NA	NA	NA
Musculo-skeletal Superficial	NA	N	N	NA	NA	NA	NA	NA	NA	NA
Other	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+Color, B+Angio, B+PW, M+Color are available in all applications as noted.
Combined mode of B+PW+Color (known as Triplex), is available on all applications EXCEPT Cardiac and Transesophageal.
[1] Small Parts: breast, scrotum and thyroid.

(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)

David A. Lilyquist
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990400

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