

K 971116

JAN 12 1998

Attachment C Intraoperative Imaging Transducer

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: 508-659-2404
Date Summary was prepared: March 3, 1997

2) **Trade Name of Platform:** Sonos 5500 Imaging System (upgrade to Sonos 2500 system)
Model Number of Transducer: 21380A
Common Name : Ultrasound Imaging System
Classification Pro Codes: 90 IYN & 90 IYQ ←

Should be 90IYN & 90IYO
90ITX also Applies
and 3/31/97

3) **Identification of Predicate Device:**

The predicate device for this submittal is the existing Intra-Operative transducer (21275A) which was reviewed by FDA on the 77030A system that was submitted as part of K944048.

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

Functionality: The new transducer has equivalent functionality to the existing transducer now being used.

Scientific Concepts: same as existing intra-operative transducer

Significant Characteristics of the Modification: The new intra-operative transducer has new patient contact materials. It is this change that creates the need to file a 510(k) with the FDA.

5) **Statement of Intended Use:** No change from existing intra-operative transducers reviewed during 510(k) K944048.

6) **Predicate Device Comparison:** There are no significant differences in safety and efficacy between the 21275A and 21380A transducers. A detailed comparison of the transducers can be found in the 510(k) report.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

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

Re: K971116
Intra-Operative Imaging Transducer 21380A
Dated: October 7, 1997
Received: October 14, 1997
Regulatory Class: II
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 21380A transducer intended for use with the SONOS 5500 System.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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.

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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 M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for David H. Seymour

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

Ultrasound Device Indications Statement
 Fill out one form for each ultrasound system or transducer
 Pg 1 of Pg 1

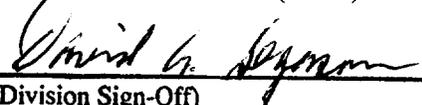
510(k) # (if known) : K971116
 Device Name: Phased Array Transducer (21380A)

Indications for Use : Diagnostic Ultrasound Imaging of the human body in the applications detailed below.

Clinical Applications	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Fetal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Abdominal	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Intra-Operative: Cardiovascular	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	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	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	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	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Cardiac Adult	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A
Cardiac Pediatric	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	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	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A
Laposcopic	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Other Indications or Modes: Combined modes are : B+M, B+M+CVI, B+PW.

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


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K971116