

JUL 24 1997

K972348

510(k) Summary of Safety and Effectiveness

per 21 CFR 807.92

- 1) **Submitter's Name / Contact Person:** Rob Butler
Address: 3000 Minuteman Road, Andover, MA 01810
Telephone Number: (508) 659-2785
Date Summary was prepared: June 23, 1997
- 2) **Trade Name:** 21336A probe for M2410A ultrasound imaging system
Common Name: endovaginal/endorectal probe for "ImagePoint" ultrasound system
Classification Pro Codes: 90-ITX, 90-IYO, and 90-IYN
- 3) **Identification of Predicate Devices:** 21370A endovaginal probe and 21371A endorectal probes used on HP-Philips SD800 ultrasound system (K935923) and HP M2410A ultrasound system (K954028)
- 4) **Description of the device or modification being submitted for premarket approval.**

Functionality: 21336A EV/ER probe has equivalent functionality to the 21370A EV and 21371A ER probes now being used with M2410A; acoustic output for 21336A is within FDA limits

Scientific Concepts: same as existing probes on M2410A

Significant Characteristics of the Modification: new patient contact materials for 21336A EV/ER probe
- 5) **Statement of Intended Use:** same as intended use for current devices (M2410A, 21370A, 21371A): endovaginal, gynecological, obstetrical, endorectal, urological (small parts - prostate)
- 6) **Predicate Device Comparison:** 21336A on M2410A is very similar to predicate devices in all respects except patient contact materials; this 510(k) submission includes biocompatibility test results which demonstrate biocompatibility for the new materials



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rob Butler
Regulatory Approval
Hewlett-Packard Medical Products Group
Hewlett-Packard Co.
3000 Minuteman Road
Andover, MA 01810-1087

JUL 24 1997

Re: K972348
HP Model 21336A Endovaginal/Endorectal Probe
Dated: June 23, 1997
Received: June 24, 1997
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Butler:

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 Image Point (HP Model 2410A) Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

21336A

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 regulation (CFR) Part 820) and that, through periodic QS inspections, the Food and

Drug Administration (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 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 February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." 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:

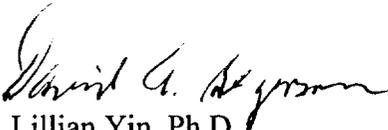
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 "dsmo@fdadr.cdrh.fda.gov".

If you have any questions regarding the content of this letter, please contact **Rodrigo C. 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

Enclosures

FDA Ultrasound Device Indications Statement

Page 1 of 1

510(k) Number (if known) : _____

Device Name: 21336A Endovaginal/Endorectal Probe for M2410A Ultrasound System

Fill out one form for each ultrasound system or transducer _____

Intended Use: Diagnostic ultrasound imaging or 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 |
| Abdominal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Intra-operative (specify) | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Intra-Operative 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 | ✓ | ✓ | ✓ | 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 Adult | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Cardiac Pediatric | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Trans-esophageal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Trans-rectal | NA | ✓ | ✓ | ✓ | NA | ✓ | ✓ | NA | ✓ | NA |
| Trans-vaginal | NA | ✓ | ✓ | ✓ | NA | ✓ | ✓ | NA | ✓ | NA |
| Intra-Luminal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Trans-urethral | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Peripheral Vessel | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Laparoscopic | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Musculo-Skeletal Conv. | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Musculo-Skeletal Superf. | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| Other (specify) | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |

Other Indications or Modes: combined modes are: B+M, B+PW

(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)

14

David A. Segorin

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972348