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Attachment D: 510(k) SUMMARY of Safety and Effectiveness

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M2410A

Device Name: This modification applies to ~~three devices~~ (Device Trade Name/ HP ~~M2406A, HP M2407A, and HP M2412A~~) in the HP SONOS Ultrasound Imaging System (Device Common Name) family, ~~and to the SD800 in the Philips Sono-Diagnost Ultrasound Imaging System family.~~

Classification Name: FDA has classified Ultrasound Imaging Systems as Class II in 21 CFR:

- 870.2100 Cardiovascular Blood Flowmeter
- 870.2120 Extravascular Blood Flow Probe
- 870.2330 Echocardiograph
- 870.2880 Ultrasonic Transducer
- 870.2890 Vessel Occlusion Transducer
- 882.1240 Echoencephalograph
- 884.2225 Obstetric-gynecologic Ultrasonic Imager
- 884.2960 Obstetric Ultrasonic Transducer and Accessories
- 892.1550 Ultrasonic Pulsed Doppler Imaging System
- 892.1560 Ultrasonic Pulsed Echo Imaging System
- 892.1570 Diagnostic Ultrasonic Transducer

In this 510(k) submission, the legally marketed devices to which we claim equivalence are the ATL HDI 3000 (K935009) and the Toshiba SSA-380A (K933743) ultrasound imaging systems.

Device Description: The modification addressed in this submission is a change from analog to digital circuit technology for the front end of the HP ultrasound imaging systems listed above.

Intended Use: This modification has no effect on intended use of the HP ultrasound systems.

Technological Characteristics: The modified HP ultrasound imaging systems will use the same type of digital circuit technology for front end receive functions as the predicate devices.

The safety of this modification is shown by compliance to medical device safety standards (such as IEC 601 and UL 2601). Software safety is verified by hazard analysis and software validation to ensure performance specifications are met. This validation, safety testing, and comparison to legally marketed devices demonstrate that the modified HP ultrasound imaging systems are substantially equivalent to legally marketed predicate devices with regards to safety, effectiveness and intended use.