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Attachment A

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: GE Medical Systems
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Product Identification: GE RT55 Diagnostic Ultrasound System

Marketed Devices: The GE RT55 is of a comparable type and substantially equivalent to the GE Medical Systems RT2800 diagnostic ultrasound system, 510(k) Number K873700, currently in commercial distribution:

Device Description: The RT55 is a portable ultrasound system weighing less than 10 kg., approximately 28 cm wide, 41 cm deep and 29 cm high with integrated monitor and keyboard. The system is designed for use in linear and convex scanning modes and supports linear, convex and micro convex probes.

Indications for Use: The RT55 portable ultrasound diagnostic system is intended for use in obstetrics, gynecology and general radiology examinations by a qualified physician to aid in the diagnosis and evaluation of soft tissues by generating two dimensional images, time-motion images and biometric data. The specific intended uses of this system include: abdominal, small parts, pediatric and fetal imaging.

Comparison with Predicate Device: The GE RT55 is comparable in key safety and effectiveness features, uses similar design, construction, and materials, and has the same intended uses and operating modes as the predicate device.

Summary of Studies: The device has been evaluated for acoustic output, biocompatibility, and thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with GMP standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE RT55 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.