

K960700

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510(k) Summary of Safety and Effectiveness

GE LOGIQ α 200 Premarket Notification - February 19, 1996

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 LOGIQ α 200 Diagnostic Ultrasound System

Marketed Devices: The GE LOGIQ α 200 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 LOGIQ α 200 diagnostic ultrasound system consists of a mobile console approximately 40 cm wide, 60 cm deep and 125 cm high, weighing approximately 70 kg. The user interface consists of a keyboard and monochrome video monitor. The system is designed for use in linear and convex scanning modes and supports linear, convex and micro convex probes. Optional image storage or hard-copy devices are integrated into the design

Indications for Use: The LOGIQ α 200 diagnostic ultrasound system is intended for use in diagnostic ultrasound imaging using B, M, and B/M combination modes in the following areas:

- Fetal
- Abdominal
- Intraoperative
- Pediatric
- Small organs including breast, neck, chest, male and female reproductive organs, limbs, and extremities
- Adult Cephalic
- Neonatal cephalic
- Adult cardiac
- Pediatric cardiac
- Trans-vaginal
- Trans-rectal

Comparison with Predicate Device: The GE LOGIQ α 200 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 LOGIQ α 200 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.