

K242925 MR Contour DL

Apr 1, 2025
189 days to decision

K242925 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k242925/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Sep 24, 2024
Decision date	Apr 1, 2025
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare
Location	Waukesha, WI, US
Contact	Allena Holzworth
Website	http://www3.gehealthcare.com/en
510(k) history	168 submissions · 168 cleared · 2004-2026

GE HealthCare is an American multinational medical technology company headquartered in Waukesha, US. The company operates globally across medical imaging, ultrasound, patient care solutions, and pharmaceutical diagnostics. GE HealthCare has received FDA 510(k) clearances from total submissions since 2004. Radiology devices represent the dominant focus, accounting for 73% of regulatory submissions. The company's latest FDA 510(k) clearance was in 2026, reflecting continued innovation in medical imaging technologies. Recent cleared devices span Radiology specialties includi...