FDA 510(k) Premarket Notification

CLEARED

K241937 Klarity SGRT System (ARSG-E1A, ARSG-E3A)

Mar 18, 2025
259 days to decision

K241937 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k241937/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 2, 2024
Decision date	Mar 18, 2025
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Klarity Medical & Equipment (GZ) Co., Ltd.**
Location	Guangzhou, CN
Contact	Guohuang Zhou
510(k) history	3 submissions · 3 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov