FDA 510(k) Premarket Notification

K202747 Klarity Bolus

CLEARED

May 14, 2021
235 days to decision

K202747 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k202747/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 21, 2020
Decision date	May 14, 2021
Days to decision	235 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	Lucy Li
510(k) history	3 submissions · 3 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Klarity Medical Products, LLC**
Contact	Peter Larson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov