

K220539 Klarity SRS Baseplate, Klarity Promise BaseplateNov 1, 2022
249 days to decisionK220539 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k220539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Feb 25, 2022
Decision date	Nov 1, 2022
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

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](https://accessdata.fda.gov)

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