

**K202747 Klarity Bolus**May 14, 2021  
235 days to decisionK202747 · Product code: IYE · Radiology  
Source: <https://www.510kdatabase.net/k202747/>**SUBMISSION DETAILS**

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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**

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Company	<b>Klarity Medical &amp; Equipment (GZ) Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Lucy Li
510(k) history	3 submissions · 3 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Klarity Medical Products, LLC</b>
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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