

K230575 Limbus ContourApr 7, 2023
37 days to decisionK230575 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k230575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 1, 2023
Decision date	Apr 7, 2023
Days to decision	37 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Limbus Ai, Inc.
Location	Regina, CA
Contact	Jon Giambattista
510(k) history	3 submissions · 3 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy
Contact	Mary Vater

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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