

K231944 CATAMARAN SI Joint Fusion SystemAug 24, 2023
55 days to decisionK231944 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k231944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jun 30, 2023
Decision date	Aug 24, 2023
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tenon Medical, Inc.
Location	San Ramon, CA, US
Contact	Susan Noreiga
510(k) history	2 submissions · 2 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Lince Consulting, LLC
Contact	Susan Noriega

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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