FDA 510(k) Premarket Notification

CLEARED

K260477 CATAMARAN™ SI Joint Fusion System

Apr 8, 2026
55 days to decision

K260477 · Product code: **OUR** · Orthopedic
Source: https://www.510kdatabase.net/k260477/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Feb 12, 2026
Decision date	Apr 8, 2026
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tenon Medical**
Location	Los Gatos, CA, US
Contact	Richard Ginn
Website	https://www.tenonmed.com
510(k) history	2 submissions · 2 cleared · 2025-2026

Tenon Medical is an orthopedic device company based in Los Gatos, California. The company specializes in sacroiliac joint fusion solutions, delivering innovative surgical options for patients with chronic sacroiliac joint pain. Tenon Medical has received FDA 510(k) clearances from total submissions since 2025. The company's regulatory portfolio is entirely focused on orthopedic devices. The latest clearance was issued in 2026, reflecting active development and market engagement. The company's flagship product is the CATAMARAN™ SI Joint Fusion System, a single-implant solu...

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Ethan Naylor

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