

K243565 DYNAMIS™ SI Screw SystemFeb 28, 2025
102 days to decisionK243565 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k243565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Nov 18, 2024
Decision date	Feb 28, 2025
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Promethean Restorative, LLC
Location	Castle Rock, CO, US
Contact	Glenn Bowman
Website	https://prometheanrestorative.com
510(k) history	3 submissions · 3 cleared · 2025-2026

Promethean Restorative, LLC is dedicated to addressing pain and suffering associated with spinal conditions. The company provides innovative solutions for stabilizing and fusing the sacroiliac joint. With a manufacturing facility in Castle Rock, Colorado, Promethean Restorative develops advanced orthopedic implants and instrumentation for spine surgery. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on orthopedic devices. First clearance in 2025 and latest clearance in 2026 demonstrate active regulatory engagement. The ...

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Device record: <https://www.510kdatabase.net/k243565/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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