

K251310 OTS 25-L (100-5)Jul 22, 2025
85 days to decisionK251310 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k251310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 28, 2025
Decision date	Jul 22, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ots Medical , Ltd.
Location	Herzliya, IL
Contact	Dekel Assaf
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

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

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