

**K241234 OTS 25-L (100-5)**Jan 23, 2025  
266 days to decisionK241234 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k241234/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 2, 2024
Decision date	Jan 23, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice Hogan

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

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241234/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026