

K251316 Mazor X System / Mazor X Stealth EditionSep 11, 2025
135 days to decisionK251316 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k251316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 29, 2025
Decision date	Sep 11, 2025
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mazor Robotics , Ltd.
Location	Kfar Saba, IL
Contact	Anat Marom
510(k) history	13 submissions · 13 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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