

**K230064 Mazor X System (Mazor X Stealth Edition)**Apr 7, 2023  
88 days to decisionK230064 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k230064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 9, 2023
Decision date	Apr 7, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mazor Robotics , Ltd.</b>
Location	Kfar Saba, IL
Contact	Rishi Sinha
510(k) history	13 submissions · 13 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230064/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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