

K140167 RENAISSANCE X SYSTEMSep 10, 2014
230 days to decisionK140167 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k140167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 23, 2014
Decision date	Sep 10, 2014
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140167/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026