FDA 510(k) Premarket Notification

K200935 Mazor X

CLEARED

May 8, 2020
30 days to decision

K200935 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k200935/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 8, 2020
Decision date	May 8, 2020
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k200935/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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