FDA 510(k) Premarket Notification

K203005 Mazor X

CLEARED

Oct 27, 2020
26 days to decision

K203005 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k203005/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 1, 2020
Decision date	Oct 27, 2020
Days to decision	26 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/k203005/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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