FDA 510(k) Premarket Notification

CLEARED

K182077 Mazor X System (Mazor X Stealth Edition)

Nov 2, 2018
93 days to decision

K182077 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k182077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 1, 2018
Decision date	Nov 2, 2018
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k182077/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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