

K201251 CarboClear Navigated InstrumentsAug 5, 2020
86 days to decisionK201251 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k201251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 11, 2020
Decision date	Aug 5, 2020
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CarboFix Orthopedics , Ltd.
Location	Herzliya, IL
Contact	Hila Wachsler-Avrahami
510(k) history	32 submissions · 32 cleared · 2011-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201251/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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