

K243958 Consolidated Operating Room Equipment (CORE) 2 Console

Mar 21, 2025
88 days to decision

K243958 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k243958/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 23, 2024
Decision date	Mar 21, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Instruments
Location	Kalamazoo, MI, US
Contact	Leandra Burke
510(k) history	72 submissions · 72 cleared · 1994-2026

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Device record: <https://www.510kdatabase.net/k243958/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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