

K252058 ROSA Knee System with UltraSound Imaging Platform (USIP)Feb 6, 2026
220 days to decisionK252058 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k252058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 1, 2025
Decision date	Feb 6, 2026
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Balmoral Medical, LLC
Location	Rosemont, IL, US
Contact	Brett Zarda
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Qserve Group, Us, Inc.
Contact	Lorry Weaver

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252058/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026