FDA 510(k) Premarket Notification

CLEARED

K252058 ROSA Knee System with UltraSound Imaging Platform (USIP)

Feb 6, 2026
220 days to decision

K252058 · 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