

K244015 SuperBall-RC™Feb 19, 2025
55 days to decisionK244015 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k244015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 26, 2024
Decision date	Feb 19, 2025
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arcuro Medical , Ltd.
Location	Misgav, IL
Contact	Lee Ranon
510(k) history	3 submissions · 3 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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