FDA 510(k) Premarket Notification

CLEARED

K251214 BEAR® (Bridge-Enhanced ACL Restoration) Implant

Jan 13, 2026
270 days to decision

K251214 · Product code: **QNI** · Orthopedic
Source: https://www.510kdatabase.net/k251214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resorbable Implant For Anterior Cruciate Ligament (acl) Repair (QNI)
Date received	Apr 18, 2025
Decision date	Jan 13, 2026
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Miach Orthopaedics, Inc.**
Location	Westborough, MA, US
Contact	Rita Paparazzo
510(k) history	3 submissions · 2 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Broderick Regulatory Consulting, LLC**
Contact	Julie Broderick

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