FDA 510(k) Premarket Notification

CLEARED

K243578 BEAR® (Bridge-Enhanced ACL Restoration) Implant

Mar 6, 2025
107 days to decision

K243578 · Product code: **QNI** · Orthopedic
Source: https://www.510kdatabase.net/k243578/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resorbable Implant For Anterior Cruciate Ligament (acl) Repair (QNI)
Date received	Nov 19, 2024
Decision date	Mar 6, 2025
Days to decision	107 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

CLINICAL EVIDENCE - NCT03348995

The BEAR III Trial for Bridge-Enhanced ACL (Anterior Cruciate Ligament) Restoration

Status	Active not recruiting - *No results published to ClinicalTrials.gov*
Enrollment	250 patients (estimated)
Study sites	11 sites
Condition studied	Anterior Cruciate Ligament Injury; Anterior Cruciate Ligament Rupture
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 17, 2034
Sponsor	Miach Orthopaedics (Industry)

Primary outcome

International Knee Documentation Committee Subjective Score (IKDC) (Survey)

Secondary outcome

Knee Injury and Osteoarthritis Score (KOOS) questionnaire

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03348995