

K252946 BioBrace® Extra-Articular Ligament Augmentation KitOct 15, 2025
30 days to decisionK252946 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k252946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Sep 15, 2025
Decision date	Oct 15, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Conmed Corporation
Location	Utica, NY, US
Contact	Amy DeLong
510(k) history	82 submissions · 82 cleared · 2004-2026

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