FDA 510(k) Premarket Notification

K242187 BioBrace®

CLEARED

Nov 27, 2024
125 days to decision

K242187 · Product code: **OWW** · Orthopedic
Source: https://www.510kdatabase.net/k242187/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement Of Tendon (OWW)
Date received	Jul 25, 2024
Decision date	Nov 27, 2024
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert Poggie

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