FDA 510(k) Premarket Notification

K251680 Biosteon® Screw

CLEARED

Feb 17, 2026
263 days to decision

K251680 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k251680/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 30, 2025
Decision date	Feb 17, 2026
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biocomposites, Ltd.**
Location	Keele, GB
Contact	Ciara Airey
Website	https://www.biocomposites.com
510(k) history	27 submissions · 27 cleared · 2000-2026

Biocomposites, Ltd. is an international medical device manufacturer based in Keele, GB. The company engineers and manufactures specialized devices for musculoskeletal infection, trauma, spine, and orthopedic applications. Biocomposites has received FDA 510(k) clearances from total submissions since 2000. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, confirming active regulatory engagement. The company's core product lines include antibiotic-loaded bone cem...

REGULATORY CONSULTANT

Consulting firm	**Bruder Consulting & Venture Group**
Contact	Scott Bruder

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