FDA 510(k) Premarket Notification

K003641 BIOLOK SCREW, BIOSTEON SCREW

CLEARED

Feb 8, 2001
73 days to decision

K003641 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k003641/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 27, 2000
Decision date	Feb 8, 2001
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biocomposites, Ltd.**
Location	Keele, GB
Contact	J.STEPHEN BRATT
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...