FDA 510(k) Premarket Notification

K081428 MODIFICATION TO DOUBLEPLAY SUTURE ANCHOR

CLEARED

Jun 20, 2008
30 days to decision

K081428 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k081428/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 21, 2008
Decision date	Jun 20, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biocomposites, Ltd.**
Location	Keele, GB
Contact	SIMON FITZER
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...