FDA 510(k) Premarket Notification

CLEARED

K243912 Newclip Patient-matched instrumentation non sterile PSI

Feb 13, 2025
56 days to decision

K243912 · Product code: **PBF** · Orthopedic
Source: https://www.510kdatabase.net/k243912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Dec 19, 2024
Decision date	Feb 13, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Newclip Technics**
Location	Haute-Goulaine, FR
Contact	Gaëlle Gourbiere
Website	https://www.newcliptechnics.com
510(k) history	31 submissions · 31 cleared · 2006-2026

Newclip Technics is a French manufacturer of orthopedic osteosynthesis solutions based in Haute-Goulaine, near Nantes. The company designs, manufactures, and markets surgical instruments and implants for hospitals and clinics worldwide. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2006. All submissions focus on orthopedic devices. The latest clearance in 2026 confirms the company remains actively engaged in regulatory submissions and product innovation. Recent cleared devices include patient-matched instrumentation sys...

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