FDA 510(k) Premarket Notification

CLEARED

K221615 Newclip Patient-matched instrumentation non sterile PSI

Oct 25, 2023
509 days to decision

K221615 · Product code: **PBF** · Orthopedic
Source: https://www.510kdatabase.net/k221615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Jun 3, 2022
Decision date	Oct 25, 2023
Days to decision	509 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Newclip Technics**
Location	Haute-Goulaine, FR
Contact	Gaelle 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 A. Poggie

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