

# K250767 Newclip Patient-matched instrumentation non sterile PSI

Oct 1, 2025  
202 days to decisionK250767 · Product code: **PBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k250767/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Mar 13, 2025
Decision date	Oct 1, 2025
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Newclip Technics</b>
Location	Haute-Goulaine, FR
Contact	Gaëlle Gourbiere
Website	<a href="https://www.newcliptechnics.com">https://www.newcliptechnics.com</a>
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

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Consulting firm	<b>BioVera, Inc.</b>
Contact	Robert Poggie

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k250767/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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