

K213214 Xpert WristNov 24, 2021
56 days to decisionK213214 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k213214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 29, 2021
Decision date	Nov 24, 2021
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	Gregoire Larche
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	The OrthoMedix Group, Inc.
Contact	J. D. Webb

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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Device record: <https://www.510kdatabase.net/k213214/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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