

K261511 Xpert Ankle

Jul 28, 2026
82 days to decision

K261511 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k261511/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 7, 2026
Decision date	Jul 28, 2026
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Newclip Technics
Location	Haute-Goulaine, FR
Contact	Gaëlle Gourbière
Website	https://www.newcliptechnics.com
510(k) history	34 submissions · 34 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...