

K141548 HIGH TIBIAL OSTEOTOMY SYSTEMJan 30, 2015
233 days to decisionK141548 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k141548/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Jun 11, 2014 |
| Decision date | Jan 30, 2015 |
| Days to decision | 233 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Newclip Technics |
| Location | Haute-Goulaine, FR |
| Contact | J.D. WEBB |
| 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...
