

K240415 Newclip Patient-matched instrumentation non sterile PSI

Nov 7, 2024
269 days to decisionK240415 · Product code: **PBF** · Orthopedic
Source: <https://www.510kdatabase.net/k240415/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopaedic Surgical Planning And Instrument Guides (PBF) |
| Date received | Feb 12, 2024 |
| Decision date | Nov 7, 2024 |
| Days to decision | 269 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Newclip Technics |
| Location | Haute-Goulaine, FR |
| Contact | Robert Poggie |
| 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...