

## K251554 Materialise TKA Guide System

Jul 14, 2025  
54 days to decisionK251554 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k251554/>

### SUBMISSION DETAILS

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received         | May 21, 2025   |
| Decision date         | Jul 14, 2025   |
| Days to decision      | 54 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

### APPLICANT

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|----------------|---|
| Company        | <b>Materialise NV</b>   |
| Location       | Leuven, BE  |
| Contact        | Giulia Girola   |
| Website        | <a href="https://www.materialise.com">https://www.materialise.com</a> |
| 510(k) history | 60 submissions · 60 cleared · 1997-2026                               |

Materialise NV is a Belgian 3D printing and additive manufacturing company headquartered in Leuven. The company specializes in digital design and 3D printing solutions for medical applications. Materialise NV has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's regulatory portfolio spans orthopedic devices, surgical planning software, and personalized surgical guides and models. Recent cleared devices include systems for knee and shoulder surgery, craniomaxillofacial surgical planning, and cardiac and thoracic imaging ...