

## K253793 Materialise TKA Guide System

Jan 6, 2026  
39 days to decisionK253793 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k253793/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 28, 2025
Decision date	Jan 6, 2026
Days to decision	39 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 ...