

## K212569 Materialise Shoulder System™, Materialise Shoulder Guide and Models, SurgiCase Shoulder Planner

Jan 12, 2022  
149 days to decision

K212569 · Product code: QHE · Orthopedic  
Source: <https://www.510kdatabase.net/k212569/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Aug 16, 2021
Decision date	Jan 12, 2022
Days to decision	149 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	Simona Beri
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 ...