

# K193560 Materialise Shoulder Guide and Models, Materialise SurgiCase Shoulder Planner, Materialise Shoulder Planner, SurgiCase Shoulder Planner, SurgiCase Planner

Mar 20, 2020  
88 days to decision

K193560 · Product code: **QHE** · Orthopedic  
Source: <https://www.510kdatabase.net/k193560/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Dec 23, 2019
Decision date	Mar 20, 2020
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Materialise NV</b>
Location	Leuven, BE
Contact	Veerle Vanderheyden
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 ...