

K260802 Materialise Shoulder System™, Materialise Shoulder Guide and Models, SurgiCase Shoulder Planner

Jun 9, 2026
90 days to decisionK260802 · Product code: QHE · Orthopedic
Source: <https://www.510kdatabase.net/k260802/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Mar 11, 2026
Decision date	Jun 9, 2026
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Materialise NV
Location	Leuven, BE
Contact	Giulia Girola
Website	https://www.materialise.com
510(k) history	61 submissions · 61 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 ...