

## K243637 Materialise Personalized Guides and Models for Craniomaxillofacial Surgery

Feb 21, 2025  
88 days to decisionK243637 · Product code: **DZJ** · Dental  
Source: <https://www.510kdatabase.net/k243637/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Driver, Wire, And Bone Drill, Manual (DZJ)
Date received	Nov 25, 2024
Decision date	Feb 21, 2025
Days to decision	88 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	Polliane Carvalho
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 ...