

K253308 Materialise Personalized Guides and Models for Craniomaxillofacial Surgery CMF Titanium Guides

Jan 7, 2026
100 days to decisionK253308 · Product code: PPT · Neurology
Source: <https://www.510kdatabase.net/k253308/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cranial Surgical Planning And Instrument Guides (PPT)
Date received	Sep 29, 2025
Decision date	Jan 7, 2026
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CMF Plastic Models

APPLICANT

Company	Materialise NV
Location	Leuven, BE
Contact	Polliane Carvalho
Website	https://www.materialise.com
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 ...