

K060950 3MATICMay 18, 2006
42 days to decisionK060950 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k060950/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 6, 2006
Decision date	May 18, 2006
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Materialise NV
Location	Leuven, BE
Contact	CARL VAN LIERDE
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 ...
