

**K053592 SIMPLANT DR. JAMES**Feb 8, 2006  
47 days to decisionK053592 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k053592/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 23, 2005
Decision date	Feb 8, 2006
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Materialise NV</b>
Location	Leuven, BE
Contact	CARL VAN LIERDE
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 ...

---