

**K091263 ZIMMER PATIENT SPECIFIC INSTRUMENTS, ZIMMER  
PATIENT SPECIFIC INSTRUMENTS PLANNER, MODEL 1.1  
(4.3.0.35)**Nov 19, 2009  
203 days to decisionK091263 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k091263/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Apr 30, 2009
Decision date	Nov 19, 2009
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Materialise NV</b>
Location	Leuven, BE
Contact	KARL VON BERGE
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 ...