

**K121640 ZIMMER PATIENT SPECIFIC INSTRUMENTS SYSTEM**Dec 5, 2012  
184 days to decisionK121640 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k121640/>**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	Jun 4, 2012
Decision date	Dec 5, 2012
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Materialise NV</b>
Location	Leuven, BE
Contact	Alexandra Razzhivina
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 ...

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