

**K173039 TruMatch CMF Titanium 3D Printed Implant**Jul 10, 2018  
285 days to decisionK173039 · Product code: **JEY** · Dental  
Source: <https://www.510kdatabase.net/k173039/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Sep 28, 2017
Decision date	Jul 10, 2018
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Materialise NV</b>
Location	Leuven, BE
Contact	Lina Ramirez
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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