K093533 ZIMMER PATIENT SPECIFIC INSTRUMENTS SYSTEM, VERSION 2.0

CLEARED

Feb 17, 2010
93 days to decision

K093533 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k093533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Nov 16, 2009
Decision date	Feb 17, 2010
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Materialise NV**
Location	Leuven, BE
Contact	KARL VOM BERGE
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 ...