**CLEARED**

# K111492 ZIMMER PATIENT SPECIFIC INSTRUMENTS PLANNER MODEL 2.5, ZIMMER PATIENT SPECIFIC INSTRUMENTS

Oct 13, 2011
135 days to decision

K111492 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k111492/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | May 31, 2011 |
| Decision date | Oct 13, 2011 |
| Days to decision | 135 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Materialise NV** |
| Location | Leuven, BE |
| Contact | Alexandra Razzhivina |
| 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 ...