

**K230540 Patient Specific Planning Solution™ 3D Bone Models**Jul 25, 2023  
148 days to decisionK230540 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k230540/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 27, 2023
Decision date	Jul 25, 2023
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biomet Manufacturing Corp</b>
Location	Warsaw, IN, US
Contact	Katherine Choi
510(k) history	93 submissions · 93 cleared · 2004-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230540/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026