FDA 510(k) Premarket Notification

CLEARED

K230540 Patient Specific Planning Solution™ 3D Bone Models

Jul 25, 2023
148 days to decision

K230540 · 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	**Biomet Manufacturing Corp**
Location	Warsaw, IN, US
Contact	Katherine Choi
510(k) history	93 submissions · 93 cleared · 2004-2023