FDA 510(k) Premarket Notification

K140652 POROUS COATED COMPREHENSIVE FRACTURE STEMS

CLEARED

Jul 3, 2014
111 days to decision

K140652 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k140652/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Mar 14, 2014
Decision date	Jul 3, 2014
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Manufacturing Corp**
Location	Warsaw, IN, US
Contact	BRIAN KINCAID
510(k) history	93 submissions · 93 cleared · 2004-2023