FDA 510(k) Premarket Notification

K173411 Comprehensive Segmental Revision System (SRS)

CLEARED

Feb 8, 2018
99 days to decision

K173411 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k173411/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Nov 1, 2017
Decision date	Feb 8, 2018
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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