FDA 510(k) Premarket Notification

K122770 BIOMET RECONSTRUCTIVE WEDGES MODEL 110003660-99, 110003797-831

CLEARED

Mar 28, 2013
199 days to decision

K122770 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k122770/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 10, 2012
Decision date	Mar 28, 2013
Days to decision	199 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