

K193038 Comprehensive Shoulder SystemOct 28, 2020
363 days to decisionK193038 · Product code: **MBF** · Orthopedic
Source: <https://www.510kdatabase.net/k193038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF)
Date received	Oct 31, 2019
Decision date	Oct 28, 2020
Days to decision	363 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

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