

K182516 Comprehensive Nano Stemless ShoulderApr 22, 2019
221 days to decisionK182516 · Product code: **PKC** · Orthopedic
Source: <https://www.510kdatabase.net/k182516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-constrained (PKC)
Date received	Sep 13, 2018
Decision date	Apr 22, 2019
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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