

**K193533 WIN Flexible Nail System**Feb 20, 2020  
62 days to decisionK193533 · Product code: **JDS** · Orthopedic  
Source: <https://www.510kdatabase.net/k193533/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nail, Fixation, Bone (JDS)
Date received	Dec 20, 2019
Decision date	Feb 20, 2020
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biomet, Inc.</b>
Location	Mchenry, IL, US
Contact	Dominique Dompore
Website	<a href="http://www.biomet.com/">http://www.biomet.com/</a>
510(k) history	440 submissions · 418 cleared · 1978-2024

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...

---