

**K190963 DePuy Synthes Craniomaxillofacial Sternal Devices -  
MR Conditional**Jul 23, 2019  
102 days to decisionK190963 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k190963/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 12, 2019
Decision date	Jul 23, 2019
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Synthes USA Products, LLC</b>
Location	West Chester, PA, US
Contact	Jeffrey Krawiec
510(k) history	60 submissions · 60 cleared · 2010-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190963/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026