

**K183011 Additive Orthopaedics Patient Specific 3D Locking Lattice Plates**Jan 10, 2019  
71 days to decisionK183011 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k183011/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 31, 2018
Decision date	Jan 10, 2019
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Additive Orthopaedics</b>
Location	Monmouth Beach, NJ, US
Contact	Gregory Kowalczyk
510(k) history	1 submissions · 1 cleared · 2019-2019

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183011/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 22, 2026