

**K180239 Additive Orthopaedics Patient Specific 3D Printed Bone Segments**May 16, 2018  
107 days to decisionK180239 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k180239/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Plate, Fixation, Bone (HRS)        |
| Date received         | Jan 29, 2018                       |
| Decision date         | May 16, 2018                       |
| Days to decision      | 107 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Additive Orthopaedics, LLC</b>     |
| Location       | Little Silver, NJ, US                 |
| Contact        | Gregory Kowalczyk                     |
| 510(k) history | 6 submissions · 6 cleared · 2016-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180239/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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