

K163593 Additive Orthopaedics Bunion SystemJun 20, 2017
181 days to decisionK163593 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k163593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 21, 2016
Decision date	Jun 20, 2017
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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