

K191047 ADI TiDAL Osteotomy WedgeNov 5, 2019
200 days to decisionK191047 · Product code: **PLF** · Orthopedic
Source: <https://www.510kdatabase.net/k191047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Wedge (PLF)
Date received	Apr 19, 2019
Decision date	Nov 5, 2019
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Additive Device, Inc. (Adi) D/B/A Restor3D
Location	Durham, NC, US
Contact	Nathan Evans
510(k) history	2 submissions · 2 cleared · 2019-2019

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