

K162179 osteo-WEDGE II ® Open Wedge Bone Locking Plate System

Jan 10, 2017
159 days to decision

K162179 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k162179/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 4, 2016
Decision date	Jan 10, 2017
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Graham Medical Technologies, LLC Db a Gramedica
Location	Macomb, MI, US
Contact	Angela Recchia
510(k) history	2 submissions · 2 cleared · 2014-2017

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Device record: <https://www.510kdatabase.net/k162179/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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