

K212334 GEO Extremity and Ankle Plating SystemSep 21, 2021
56 days to decisionK212334 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k212334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 27, 2021
Decision date	Sep 21, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gramercy Extremity Orthopedics, LLC
Location	Richardson, TX, US
Contact	Michael P. Simpson
510(k) history	5 submissions · 5 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Novus Management Group
Contact	Tamala Wampler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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