

K210534 GEO FirstFUSE 1st MTP Joint Arthrodesis Plating SystemMar 26, 2021
30 days to decisionK210534 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k210534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 24, 2021
Decision date	Mar 26, 2021
Days to decision	30 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, LLC
Contact	Tamala J. Wampler

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210534/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026