

K213005 Apollo Ankle Fracture Plating SystemMar 11, 2022
172 days to decisionK213005 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k213005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 20, 2021
Decision date	Mar 11, 2022
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Glw Medical, Inc.
Location	Englewood Cliff, NJ, US
Contact	Arundhati Radhakrishnan
510(k) history	2 submissions · 2 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Wagoner Consulting, LLC
Contact	Cheryl Wagoner

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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