

K201379 Artemis Proximal Femoral Nail SystemFeb 19, 2021
269 days to decisionK201379 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k201379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 26, 2020
Decision date	Feb 19, 2021
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Glw, Inc.
Location	Englewood Cliff, NJ, US
Contact	Arundhati Radhakrishnan
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Lincé Consulting, LLC
Contact	Nancy Lincé

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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