

K221907 RhinAer® Stylus (FG1393)Jul 29, 2022
29 days to decisionK221907 · Product code: **GEI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k221907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 30, 2022
Decision date	Jul 29, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aerin Medical, Inc.
Location	Sunnyvale, CA, US
Contact	Shannon Scott
510(k) history	9 submissions · 9 cleared · 2015-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221907/> 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