

K200300 VivAer StylusApr 13, 2020
67 days to decisionK200300 · Product code: **GEI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k200300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 6, 2020
Decision date	Apr 13, 2020
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200300/> 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