

**K223911 Lumen 155-SF**Oct 17, 2023  
292 days to decisionK223911 · Product code: **QDD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k223911/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Prescription (QDD)
Date received	Dec 29, 2022
Decision date	Oct 17, 2023
Days to decision	292 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Intricon Corporation</b>
Location	Arden Hills, MN, US
Contact	David Akbari
510(k) history	1 submissions · 1 cleared · 2023-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223911/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026