

**K231550 Sontro® OTC Hearing Aids (AI)**Oct 26, 2023  
149 days to decisionK231550 · Product code: **QUH** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k231550/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Over The Counter (QUH)
Date received	May 30, 2023
Decision date	Oct 26, 2023
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Soundwave Hearing, LLC</b>
Location	Oak Brook, IL, US
Contact	Anthony Florek
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Rook Quality Systems, Inc.</b>
Contact	Kyle Rose

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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