

K221064 Nuheara IQbuds 2 PRO Hearing AidOct 30, 2022
202 days to decisionK221064 · Product code: **QUH** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k221064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Over The Counter (QUH)
Date received	Apr 11, 2022
Decision date	Oct 30, 2022
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nuheara Limited
Location	Bellevue, WA, US
Contact	John Luna
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Darthur Consulting
Contact	Deborah Arthur

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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