

**K233649 ALGO Pro Newborn Hearing Screener (ALGO Pro)**Mar 8, 2024  
115 days to decisionK233649 · Product code: **GWJ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k233649/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Nov 14, 2023
Decision date	Mar 8, 2024
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Natus Medical Incorporated Db a Excel-Tech Ltd. (Xitek)</b>
Location	Oakville, CA
Contact	Bronwyn Kelly
510(k) history	13 submissions · 13 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233649/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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