

K242198 ICS Dizcovery (1091)Feb 14, 2025
203 days to decisionK242198 · Product code: **GWN** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k242198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Jul 26, 2024
Decision date	Feb 14, 2025
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Natus Medical Denmark Aps
Location	Taastrup, DK
Contact	Therese Coffey
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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