

**K222671 DeltaScan Patch**Feb 2, 2023  
149 days to decisionK222671 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k222671/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 6, 2022
Decision date	Feb 2, 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>Prolira B.V.</b>
Location	Utrecht, NL
Contact	Rutger O. van Merkerk
510(k) history	2 submissions · 2 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Corolla Clin/Reg Consulting</b>
Contact	Paul J Manberg

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/k222671/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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