FDA 510(k) Premarket Notification

# K222671 DeltaScan Patch

**CLEARED**

Feb 2, 2023
149 days to decision

K222671 · 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

| | |
|---|---|
| Company | **Prolira B.V.** |
| Location | Utrecht, NL |
| Contact | Rutger O. van Merkerk |
| 510(k) history | 2 submissions · 2 cleared · 2023-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Corolla Clin/Reg Consulting** |
| Contact | Paul J Manberg |

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