

K221123 WISE Cortical Strip (WCS)Nov 22, 2022
218 days to decisionK221123 · Product code: **GYC** · Neurology
Source: <https://www.510kdatabase.net/k221123/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Cortical (GYC) |
| Date received | Apr 18, 2022 |
| Decision date | Nov 22, 2022 |
| Days to decision | 218 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Wise S.R.L. |
| Location | Cologno Monzese, IT |
| Contact | Luca Ravagnan |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------|
| Consulting firm | Decus Biomedical |
| Contact | Terri Bogucki |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221123/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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