FDA 510(k) Premarket Notification

# K220530 Tetragraph Neuromuscular Transmission Monitor

**CLEARED**

Aug 17, 2022
174 days to decision

K220530 · Product code: **KOI** · Anesthesiology
Source: https://www.510kdatabase.net/k220530/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Peripheral, Electric (KOI) |
| Date received | Feb 24, 2022 |
| Decision date | Aug 17, 2022 |
| Days to decision | 174 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Senzime AB** |
| Location | Uppsala, SE |
| Contact | Johanna Faris |
| 510(k) history | 2 submissions · 2 cleared · 2019-2022 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Obelix Consulting** |
| Contact | Elisa Maldonado-Holmertz |

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