

**K261098 TetraGraph Neuromuscular Transmission Monitor  
(SEN 2015)Accessories:TetraSens (SEN 2012)TetraSens  
Pediatric (SEN 2013)TetraSensitive (SEN 2016)TetraHub (SEN  
2017)**May 22, 2026  
50 days to decisionK261098 · Product code: **KOI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k261098/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Peripheral, Electric (KOI)
Date received	Apr 2, 2026
Decision date	May 22, 2026
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Senzime AB</b>
Location	Uppsala, SE
Contact	Johanna Faris
510(k) history	3 submissions · 3 cleared · 2019-2026

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Obelix Consulting, LLC</b>
Contact	Elisa Maldonado-Holmertz

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261098/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 5, 2026