CLEARED

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 decision

K261098 · 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	**Senzime AB**
Location	Uppsala, SE
Contact	Johanna Faris
510(k) history	3 submissions · 3 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**Obelix Consulting, LLC**
Contact	Elisa Maldonado-Holmertz

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