

K241785 StarFormer (M008-3T)Mar 27, 2025
280 days to decisionK241785 · Product code: **QPL** · Physical MedicineSource: <https://www.510kdatabase.net/k241785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromagnetic Stimulator, Pain Relief (QPL)
Date received	Jun 20, 2024
Decision date	Mar 27, 2025
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fotona D.O.O.
Location	Ljubljana, SI
Contact	Tina Bartolic
510(k) history	16 submissions · 16 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241785/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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