

K253408 CoolToneJan 16, 2026
108 days to decisionK253408 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k253408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Sep 30, 2025
Decision date	Jan 16, 2026
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer Medizinsysteme GmbH
Location	Neu-Ulm, DE
Contact	Ute Killet
510(k) history	13 submissions · 13 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253408/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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