

K251378 CoolToneJul 14, 2025
73 days to decisionK251378 · Product code: **NGX** · Physical Medicine
Source: <https://www.510kdatabase.net/k251378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	May 2, 2025
Decision date	Jul 14, 2025
Days to decision	73 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

REGULATORY CONSULTANT

Consulting firm	Qara Consulting
Contact	Scott Blood

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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