

K192940 CoolToneNov 15, 2019
28 days to decisionK192940 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k192940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Oct 18, 2019
Decision date	Nov 15, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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