

K191075 HealyNov 22, 2019
213 days to decisionK191075 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k191075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Apr 23, 2019
Decision date	Nov 22, 2019
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Timewaver Production GmbH
Location	Kranzlin, DE
Contact	Martin Wittmann
510(k) history	2 submissions · 2 cleared · 2019-2021

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