

K162517 Electronic Pulse Stimulator Model: PL-029K12 and PL-029K13

Apr 14, 2017
217 days to decision

K162517 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k162517/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 9, 2016
Decision date	Apr 14, 2017
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jkh Health Co., Ltd.
Location	Shenzhen, CN
Contact	Pu Jiang
510(k) history	10 submissions · 10 cleared · 2016-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162517/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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