

K163166 EASYWELL TENS System TENS and Heat, EASYWELL TENS System TENS only

Aug 11, 2017
270 days to decision

K163166 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k163166/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Nov 14, 2016
Decision date	Aug 11, 2017
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Easywell Biomedicals, Inc.
Location	Hsinchu, TW
Contact	ARTHUR CHEN
510(k) history	2 submissions · 2 cleared · 2017-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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