

K122410 I RUNE (I-200L)Nov 12, 2013
461 days to decisionK122410 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k122410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 8, 2012
Decision date	Nov 12, 2013
Days to decision	461 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medirune Co, Ltd.
Location	Gangnam-Gu, KR
Contact	YANG HO DONG
510(k) history	1 submissions · 1 cleared · 2013-2013

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