FDA 510(k) Premarket Notification

K150681 GEMORE OTC TENS

CLEARED

May 12, 2015
56 days to decision

K150681 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k150681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Mar 17, 2015
Decision date	May 12, 2015
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gemore Technology Co, Ltd.**
Location	Tan Shui, Taipei Hsien, TW
Contact	Boden S.P Lai
510(k) history	14 submissions · 14 cleared · 2003-2019