FDA 510(k) Premarket Notification

CLEARED

K150941 Somnowell Mandibular Advancement Appliance (MAA)

May 22, 2015
44 days to decision

K150941 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k150941/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Apr 8, 2015
Decision date	May 22, 2015
Days to decision	44 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Somnowell , Ltd.**
Location	London, GB
Contact	Simon Ash
510(k) history	1 submissions · 1 cleared · 2015-2015