FDA 510(k) Premarket Notification

K191320 Slow Wave DS8

CLEARED

Oct 2, 2020
506 days to decision

K191320 · Product code: **LQZ** · Dental
Source: https://www.510kdatabase.net/k191320/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Jaw Repositioning (LQZ)
Date received	May 15, 2019
Decision date	Oct 2, 2020
Days to decision	506 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Slow Wave, Inc.**
Location	Spicewood, TX, US
Contact	Wayne R. Wagner
510(k) history	2 submissions · 2 cleared · 2020-2024