FDA 510(k) Premarket Notification

K182947 Dental Pain Eraser

CLEARED

Mar 26, 2019
154 days to decision

K182947 · Product code: **LWM** · Dental
Source: https://www.510kdatabase.net/k182947/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Electrical Dental Anesthesia (LWM)
Date received	Oct 23, 2018
Decision date	Mar 26, 2019
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Synapse Dental, LLC**
Location	Cranston, RI, US
Contact	Cosmo Haralambidis
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Experien Group, LLC**
Contact	Valerie Defiesta-Ng

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov