FDA 510(k) Premarket Notification

K193570 Dental Pain Eraser

CLEARED

Jan 17, 2020
25 days to decision

K193570 · Product code: **LWM** · Dental
Source: https://www.510kdatabase.net/k193570/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Electrical Dental Anesthesia (LWM)
Date received	Dec 23, 2019
Decision date	Jan 17, 2020
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Synapse Dental**
Location	Cranston, RI, US
Contact	Cosmo Haralambidis
510(k) history	2 submissions · 2 cleared · 2020-2020

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