FDA 510(k) Premarket Notification

K213477 Root ZX3

CLEARED

Aug 3, 2022
278 days to decision

K213477 · Product code: **EKZ** · Dental
Source: https://www.510kdatabase.net/k213477/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, And Accessories, Dental (EKZ)
Date received	Oct 29, 2021
Decision date	Aug 3, 2022
Days to decision	278 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**J. Morita USA, Inc.**
Location	Irvine, CA, US
Contact	Fujio Zushi
510(k) history	52 submissions · 52 cleared · 1988-2022

REGULATORY CONSULTANT

Consulting firm	**Fish & Richardson, P.C.**
Contact	Keith A. Barritt

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