FDA 510(k) Premarket Notification

K031204 DENTAPORT ZX

CLEARED

Aug 21, 2003
127 days to decision

K031204 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k031204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Apr 16, 2003
Decision date	Aug 21, 2003
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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