FDA 510(k) Premarket Notification

K003714 OSSTELL RESONANCE FREQUENCY ANALYZER

CLEARED

Aug 9, 2001
251 days to decision

K003714 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k003714/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Dec 1, 2000
Decision date	Aug 9, 2001
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Integration Diagnostics, Ltd.**
Location	Findley, MN, US
Contact	CONSTANCE BUNDY
510(k) history	2 submissions · 2 cleared · 2001-2004