FDA 510(k) Premarket Notification

K082325 APEXUM ABLATOR

CLEARED

Apr 21, 2009
250 days to decision

K082325 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k082325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Aug 14, 2008
Decision date	Apr 21, 2009
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Apexum , Ltd.**
Location	Or Yehuda, IL
Contact	IDAN TOBIS
510(k) history	1 submissions · 1 cleared · 2009-2009