FDA 510(k) Premarket Notification

K123582 ENDO A CLASS

CLEARED

Aug 16, 2013
269 days to decision

K123582 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k123582/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Nov 20, 2012
Decision date	Aug 16, 2013
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Saeyang Microtech Co., Ltd.**
Location	Great Neck, NY, US
Contact	JIGAR SHAH
510(k) history	4 submissions · 4 cleared · 2013-2022