

K123582 ENDO A CLASSAug 16, 2013
269 days to decisionK123582 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026