

K252223 Alpha Endo Handpiece (Alpha Endo)Oct 16, 2025
92 days to decisionK252223 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k252223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Jul 16, 2025
Decision date	Oct 16, 2025
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SHENZHEN SUPERLINE TECHNOLOGY CO., LTD.
Location	Shenzhen, CN
Contact	Jinsong Zhou
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252223/> 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 13, 2026