

K213897 Pro M ClassSep 19, 2022
279 days to decisionK213897 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k213897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Dec 14, 2021
Decision date	Sep 19, 2022
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	DongHa Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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