

K210475 EQ-MSep 21, 2022
581 days to decisionK210475 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k210475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Feb 17, 2021
Decision date	Sep 21, 2022
Days to decision	581 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meta Systems Co., Ltd.
Location	Seoul, KR
Contact	Yang Ho Dong
510(k) history	4 submissions · 4 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	Onbix Corporation
Contact	Yang Ho Dong

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

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