

K212043 TRAUS ENDOJun 24, 2022
359 days to decisionK212043 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k212043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Jun 30, 2021
Decision date	Jun 24, 2022
Days to decision	359 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Saeshin Precision Co., Ltd.
Location	Seoul, KR
Contact	Nam-Gung San
510(k) history	18 submissions · 18 cleared · 2009-2026

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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