

K143411 TRAUS ENDOJun 29, 2015
213 days to decisionK143411 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k143411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Nov 28, 2014
Decision date	Jun 29, 2015
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Saeshin Precision Co., Ltd.
Location	Seoul, KR
Contact	Sae Kwan Choi
510(k) history	18 submissions · 18 cleared · 2009-2026

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