

K201292 TRAUS SIP20Feb 11, 2021
273 days to decisionK201292 · Product code: **EBW** · Dental
Source: <https://www.510kdatabase.net/k201292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	May 14, 2020
Decision date	Feb 11, 2021
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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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