

**K251407 Motor Handpiece and Control Unit (SDI10)**Jan 30, 2026  
269 days to decisionK251407 · Product code: **EBW** · Dental  
Source: <https://www.510kdatabase.net/k251407/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	May 6, 2025
Decision date	Jan 30, 2026
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Saeshin Precision Co., Ltd.</b>
Location	Seoul, KR
Contact	San NamGung
510(k) history	18 submissions · 18 cleared · 2009-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>E &amp; M</b>
Contact	Sanghwa Myung

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251407/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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