

K243911 HPR Cordless Hygiene HandpieceDec 20, 2024
1 days to decisionK243911 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k243911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Dec 19, 2024
Decision date	Dec 20, 2024
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Handpiece Headquarters
Location	Placentia, CA, US
Contact	Frederick Wang
510(k) history	6 submissions · 6 cleared · 2009-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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