

K221814 OK HandpieceJul 15, 2022
23 days to decisionK221814 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k221814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Jun 22, 2022
Decision date	Jul 15, 2022
Days to decision	23 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jaintek Co.,Ltd
Location	Ansan-Si, KR
Contact	Jung Gun Lee
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

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