

K202371 Highspeed Airturbine HandpieceNov 8, 2021
446 days to decisionK202371 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k202371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Aug 19, 2020
Decision date	Nov 8, 2021
Days to decision	446 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Dongbo Dental Handpiece Co., Ltd.
Location	Beijing, CN
Contact	Chao Hao
510(k) history	2 submissions · 2 cleared · 2018-2021

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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