

K233308 Air Motor (Model name: FX204 M4)Apr 25, 2024
209 days to decisionK233308 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k233308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Sep 29, 2023
Decision date	Apr 25, 2024
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Air Motor (Model name: M205)

APPLICANT

Company	Nakanishi, Inc.
Location	Kanuma, JP
Contact	Masaaki Kikuchi
Website	https://www.nakanishi-inc.com
510(k) history	40 submissions · 40 cleared · 2001-2026

Nakanishi, Inc. is a precision medical device manufacturer based in Kanuma, Japan. The company specializes in motorized spindles and micro grinders for medical and industrial applications. Nakanishi has received FDA 510(k) clearances from total submissions since its first clearance in 2001. Dental devices represent the dominant category, accounting for 88% of the company's regulatory submissions. The company remains active, with its latest FDA 510(k) clearance in 2026. Recent cleared devices include motorized systems for dental surgery and scaling, air-powered polishing i...

REGULATORY CONSULTANT

Consulting firm	Globizz Corpration
Contact	Takahiro Haruyama

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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Device record: <https://www.510kdatabase.net/k233308/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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