

K241880 Air Powered Tooth Polishing System (Perio-Mate)Sep 20, 2024
84 days to decisionK241880 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k241880/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Jun 28, 2024
Decision date	Sep 20, 2024
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Air Powered Tooth Polishing System (Perio Mate Nozzle Tip)

APPLICANT

Company	Nakanishi, Inc.
Location	Kanuma, JP
Contact	Kikuchi Masaaki
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...