

**K032395 PROPHY-MATE**Oct 17, 2003  
74 days to decisionK032395 · Product code: **EFB** · Dental  
Source: <https://www.510kdatabase.net/k032395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Aug 4, 2003
Decision date	Oct 17, 2003
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Nakanishi, Inc.</b>
Location	Kanuma, JP
Contact	HIROJI SEKIGUCHI
Website	<a href="https://www.nakanishi-inc.com">https://www.nakanishi-inc.com</a>
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...

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