

**K113655 TI-MAX X TURBINE**Mar 5, 2012  
84 days to decisionK113655 · Product code: **EFB** · Dental  
Source: <https://www.510kdatabase.net/k113655/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Dec 12, 2011
Decision date	Mar 5, 2012
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nakanishi, Inc.</b>
Location	Kanuma, JP
Contact	DIANE RUTHERFORD
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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