

**K131578 IPROPHY MOBILE**Sep 12, 2013  
104 days to decisionK131578 · Product code: **EKX** · Dental  
Source: <https://www.510kdatabase.net/k131578/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	May 31, 2013
Decision date	Sep 12, 2013
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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...

---