

**K031421 ULTRASONIC SCALER, MODELS VARIOS 350 LUX,  
VARIOS 350 (NO LIGHT), VARIOS 550, VARIOS 150 LUX,  
VARIOS 150 (NO LIGHT)**Mar 26, 2004  
326 days to decisionK031421 · Product code: ELC · Dental  
Source: <https://www.510kdatabase.net/k031421/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	May 5, 2003
Decision date	Mar 26, 2004
Days to decision	326 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Nakanishi, Inc.</b>
Location	Kanuma, JP
Contact	MASAYUKI ONOBUCHI
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...