

**K251689 VARIOS 170 LUX SCALER SYSTEM (VA170LUXS10)**Sep 19, 2025  
109 days to decisionK251689 · Product code: **ELC** · Dental  
Source: <https://www.510kdatabase.net/k251689/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Jun 2, 2025
Decision date	Sep 19, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VARIOS 170 LUX SCALER SYSTEM (VA170LUXS11); VARIOS 170 SCALER SYSTEM (VA170S11)

**APPLICANT**

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Company	<b>Nakanishi, Inc.</b>
Location	Kanuma, JP
Contact	Kikuchi Masaaki
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...