

**K222518 FX Contra**Nov 17, 2022  
90 days to decisionK222518 · Product code: **EGS** · Dental  
Source: <https://www.510kdatabase.net/k222518/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Contra- And Right-angle Attachment, Dental (EGS)
Date received	Aug 19, 2022
Decision date	Nov 17, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ken Block Consulting, LLC</b>
Contact	Yulia Nikova

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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