

K233117 Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)Jun 20, 2024
267 days to decisionK233117 · Product code: **EBW** · Dental
Source: <https://www.510kdatabase.net/k233117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	Sep 27, 2023
Decision date	Jun 20, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nakanishi, Inc.
Location	Kanuma, JP
Contact	Masaaki Kikuchi
Website	https://www.nakanishi-inc.com
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...