

K011926 ELEC-MATE ESep 11, 2001
83 days to decisionK011926 · Product code: **EBW** · Dental
Source: <https://www.510kdatabase.net/k011926/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	Jun 20, 2001
Decision date	Sep 11, 2001
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nakanishi, Inc.
Location	Kanuma, JP
Contact	HIROJI SEKIGUCHI
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...
