FDA 510(k) Premarket Notification

K211584 Oral Surgery Contra

CLEARED

Aug 19, 2021
87 days to decision

K211584 · Product code: **KMW** · Dental
Source: https://www.510kdatabase.net/k211584/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Rotary Bone Cutting (KMW)
Date received	May 24, 2021
Decision date	Aug 19, 2021
Days to decision	87 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...

REGULATORY CONSULTANT

Consulting firm	**Ken Block Consulting, LLC**
Contact	Yulia Nikova

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