FDA 510(k) Premarket Notification

K121901 TI-MAX Z45

CLEARED

Feb 28, 2013
244 days to decision

K121901 · Product code: **EGS** · Dental
Source: https://www.510kdatabase.net/k121901/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Contra- And Right-angle Attachment, Dental (EGS)
Date received	Jun 29, 2012
Decision date	Feb 28, 2013
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nakanishi, Inc.**
Location	Kanuma, JP
Contact	FUMIAKI KANAI
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...