FDA 510(k) Premarket Notification

K073678 VARIOSURG

CLEARED

Jul 10, 2008
195 days to decision

K073678 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k073678/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Dec 28, 2007
Decision date	Jul 10, 2008
Days to decision	195 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Nakanishi, Inc.**
Location	Kanuma, JP
Contact	KEITH BARRITT
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...