

K083112 PRIMADOApr 29, 2009
190 days to decisionK083112 · Product code: **HBC** · Neurology
Source: <https://www.510kdatabase.net/k083112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Motor, Drill, Electric (HBC)
Date received	Oct 21, 2008
Decision date	Apr 29, 2009
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nakanishi, Inc.
Location	Kanuma, JP
Contact	KEITH A 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...
