

K132264 PRIMADO2 TOTAL SURGICAL SYSTEMDec 17, 2013
148 days to decisionK132264 · Product code: **HBC** · Neurology
Source: <https://www.510kdatabase.net/k132264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Motor, Drill, Electric (HBC)
Date received	Jul 22, 2013
Decision date	Dec 17, 2013
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nakanishi, Inc.
Location	Kanuma, JP
Contact	DIANE RUTHERFORD
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...
