FDA 510(k) Premarket Notification

K202120 P300 Attachment

CLEARED

Oct 22, 2021
449 days to decision

K202120 · Product code: **HBE** · Neurology
Source: https://www.510kdatabase.net/k202120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Jul 30, 2020
Decision date	Oct 22, 2021
Days to decision	449 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	Gregory Woodard

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