

K080722 PRIMADO SURGICAL DRILLSep 17, 2008
188 days to decisionK080722 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k080722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Mar 13, 2008
Decision date	Sep 17, 2008
Days to decision	188 days
Third-party review	No
Summary / Statement	Statement

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...
