FDA 510(k) Premarket Notification

CLEARED

K211531 Cordless Prophy System, Model: i-Polish

Dec 17, 2021
214 days to decision

K211531 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k211531/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	May 17, 2021
Decision date	Dec 17, 2021
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guilin Woodpecker Medical Instrument Co., Ltd.**
Location	Flintville, TN, US
Contact	Ning Jiakang
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Yoyo Chen

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