FDA 510(k) Premarket Notification

K211721 PS System

CLEARED

Dec 2, 2021
181 days to decision

K211721 · Product code: **NYL** · Dental
Source: https://www.510kdatabase.net/k211721/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Root Canal Irrigation (NYL)
Date received	Jun 4, 2021
Decision date	Dec 2, 2021
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inter-Med, Inc.**
Location	Racine, WI, US
Contact	Brett Arand
510(k) history	8 submissions · 8 cleared · 2009-2026