FDA 510(k) Premarket Notification

K233935 DigiLine Direct Print Aligner System

CLEARED

Apr 5, 2024
113 days to decision

K233935 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k233935/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Dec 14, 2023
Decision date	Apr 5, 2024
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Park Dental Research Corporation**
Location	Ardmore, OK, US
Contact	Logan Simmons
510(k) history	3 submissions · 3 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Logan Simmons

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