

K252976 Park Dental Nylon MADDec 18, 2025
92 days to decisionK252976 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k252976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Sep 17, 2025
Decision date	Dec 18, 2025
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Park Dental Research Corp.
Location	New York, NY, US
Contact	Ron Bulard
510(k) history	4 submissions · 4 cleared · 1986-2025

REGULATORY CONSULTANT

Consulting firm	Prime Path Medtech
Contact	Jennifer Day

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

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