FDA 510(k) Premarket Notification

CLEARED

K230532 RADx Intraoral Appliance for Snoring and Sleep Apnea

Jul 12, 2023
135 days to decision

K230532 · Product code: **LQZ** · Dental
Source: https://www.510kdatabase.net/k230532/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Device, Jaw Repositioning (LQZ)
Date received	Feb 27, 2023
Decision date	Jul 12, 2023
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Achaemenid, LLC**
Location	Stratford, CT, US
Contact	Rachel Miller
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Aztech Regulatory & Quality, LLC**
Contact	Joseph Azary

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230532/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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