FDA 510(k) Premarket Notification

K232657 InnerView LC

CLEARED

Sep 1, 2023
1 days to decision

K232657 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k232657/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Aug 31, 2023
Decision date	Sep 1, 2023
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Perimetrics, Inc.**
Location	Mission Viejo, CA, US
Contact	Alicia Mszyca
510(k) history	3 submissions · 3 cleared · 2008-2025

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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