

K243427 QuickSleeper 5Aug 1, 2025
269 days to decisionK243427 · Product code: **EGM** · Dental
Source: <https://www.510kdatabase.net/k243427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Jet, Mechanical-powered (EGM)
Date received	Nov 5, 2024
Decision date	Aug 1, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentahitec
Location	Mazieres En Mauges, FR
Contact	Olivier Villette
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Qrs Solutions, LLC
Contact	Adrienne von Foller

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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