

K201785 EPIEN Dental CleanserSep 9, 2021
436 days to decisionK201785 · Product code: **KJJ** · DentalSource: <https://www.510kdatabase.net/k201785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cleanser, Root Canal (KJJ)
Date received	Jun 30, 2020
Decision date	Sep 9, 2021
Days to decision	436 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Epien Medical, Inc.
Location	Washington, DC, US
Contact	Reginald Dupre
510(k) history	2 submissions · 2 cleared · 2013-2021

REGULATORY CONSULTANT

Consulting firm	The Allis Law Firm, PLLC
Contact	Carmelina G. Allis

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/k201785/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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