

K182712 DEXIS CariVu 3-in-1 by KaVoNov 23, 2019
422 days to decisionK182712 · Product code: **NTK** · Dental
Source: <https://www.510kdatabase.net/k182712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Caries Detector, Laser Light, Transmission (NTK)
Date received	Sep 27, 2018
Decision date	Nov 23, 2019
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kaltenbach & Voigt GmbH
Location	Orange, CA, US
Contact	Stefan Trampler
510(k) history	9 submissions · 9 cleared · 2011-2019

REGULATORY CONSULTANT

Consulting firm	Kavo Dental Technologies, LLC
Contact	Frank Ray

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/k182712/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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