

K181110 PROPHYflex 4Apr 10, 2019
348 days to decisionK181110 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k181110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Apr 27, 2018
Decision date	Apr 10, 2019
Days to decision	348 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/k181110/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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