FDA 510(k) Premarket Notification

# K181110 PROPHYflex 4

**CLEARED**

Apr 10, 2019
348 days to decision

K181110 · Product code: **EFB** · Dental
Source: https://www.510kdatabase.net/k181110/

## SUBMISSION DETAILS

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|---|---|
| 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