

K210977 E-Dent 1000May 25, 2021
54 days to decisionK210977 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k210977/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received | Apr 1, 2021 |
| Decision date | May 25, 2021 |
| Days to decision | 54 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Envisiontec GmbH |
| Location | Gladbeck, DE |
| Contact | Ruediger van Bernum |
| 510(k) history | 5 submissions · 5 cleared · 2020-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------|
| Consulting firm | Qserve Group, Us, Inc. |
| Contact | Patsy J. Trisler |

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

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