

K252430 Freeprint® denture flexOct 30, 2025
90 days to decisionK252430 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k252430/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received | Aug 1, 2025 |
| Decision date | Oct 30, 2025 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Detax GmbH |
| Location | Ettingen, DE |
| Contact | Barabara Voigt |
| 510(k) history | 3 submissions · 3 cleared · 2022-2025 |

REGULATORY CONSULTANT

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|-----------------|--------------------|
| Consulting firm | Aclivi, LLC |
| Contact | Chris Brown |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252430/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026