

K240435 Alpha Dent Implants Dental Implants SystemDec 20, 2024
310 days to decisionK240435 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k240435/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Feb 14, 2024 |
| Decision date | Dec 20, 2024 |
| Days to decision | 310 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Alpha Dent Implants GmbH |
| Location | Pforzheim, DE |
| Contact | Simha Sibony |
| 510(k) history | 2 submissions · 2 cleared · 2021-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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