

K242661 TRI-matrix® X-Force ImplantsJan 8, 2025
126 days to decisionK242661 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k242661/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Sep 4, 2024 |
| Decision date | Jan 8, 2025 |
| Days to decision | 126 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Tri Dental Implants Int. AG |
| Location | Baar, CH |
| Contact | Sandro Venanzoni |
| 510(k) history | 3 submissions · 3 cleared · 2015-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------------|
| Consulting firm | PaxMed International, LLC |
| Contact | Floyd Larson |

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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