

**K203660 TRI-matrix Implant Line**Dec 21, 2021  
371 days to decisionK203660 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k203660/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Dec 15, 2020                         |
| Decision date         | Dec 21, 2021                         |
| Days to decision      | 371 days                             |
| Third-party review    | No                                   |
| Combination product   | No                                   |
| PCCP authorized       | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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

**REGULATORY CONSULTANT**

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|-----------------|----------------------------------|
| Consulting firm | <b>PaxMed International, LLC</b> |
| Contact         | Floyd G. 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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