

K220841 PrimeTaper EV Dental Implants Ø3.0, DS Implants abutments with EV connection (XS)

Nov 16, 2022
238 days to decisionK220841 · Product code: DZE · Dental
Source: <https://www.510kdatabase.net/k220841/>

SUBMISSION DETAILS

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Mar 23, 2022 |
| Decision date | Nov 16, 2022 |
| Days to decision | 238 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dentsply Sirona |
| Location | York, PA, US |
| Contact | Courtney Clark |
| Website | https://www.dentsplysirona.com |
| 510(k) history | 65 submissions · 65 cleared · 2016-2026 |

Dentsply Sirona is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company markets products in over 120 countries and operates factories across 21 nations. Dentsply Sirona has received FDA 510(k) clearances from total submissions since 2016. Dental devices represent 78% of the company's regulatory submissions, reflecting its core focus on laboratory equipment, specialty products, and consumables including abutments, CAD/CAM blocks, and restorative materials. The company's latest clearance in 2026 demonstrates continued reg...