

K222497 Zaga Zygomatic SystemNov 9, 2022
83 days to decisionK222497 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k222497/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Aug 18, 2022 |
| Decision date | Nov 9, 2022 |
| Days to decision | 83 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Southern Implants (Pty), Ltd. |
| Location | Irene, ZA |
| Contact | Leith C. Cumming |
| 510(k) history | 19 submissions · 19 cleared · 2016-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222497/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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