

**K192651 ZAGA Zygomatic System**May 7, 2020  
226 days to decisionK192651 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k192651/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 24, 2019
Decision date	May 7, 2020
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Southern Implants (Pty), Ltd.</b>
Location	Irene, ZA
Contact	Lauranda G Breytenbach
510(k) history	19 submissions · 19 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192651/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026