

K232418 Single Platform SP1 Implant SystemDec 1, 2023
112 days to decisionK232418 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k232418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 11, 2023
Decision date	Dec 1, 2023
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Southern Implants (Pty), Ltd.
Location	Irene, ZA
Contact	Colin Saffy
510(k) history	19 submissions · 19 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232418/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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