

K163634 External Hex ImplantsNov 6, 2017
319 days to decisionK163634 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k163634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 22, 2016
Decision date	Nov 6, 2017
Days to decision	319 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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