

K161548 Osseointegrated FixturesDec 1, 2016
181 days to decisionK161548 · Product code: **FZE** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Nose, Internal (FZE)
Date received	Jun 3, 2016
Decision date	Dec 1, 2016
Days to decision	181 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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