

K221447 Southern Anterior Screw Fixated Cage (SASCA)Oct 14, 2022
149 days to decisionK221447 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k221447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	May 18, 2022
Decision date	Oct 14, 2022
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Southern Medical (Pty) , Ltd.
Location	Irene, ZA
Contact	Dalene Styger
510(k) history	6 submissions · 6 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
Contact	Nathan Wright

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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