

K230608 SPICCA Stand-Alone Cervical Fusion CagesAug 14, 2023
164 days to decisionK230608 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k230608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Mar 3, 2023
Decision date	Aug 14, 2023
Days to decision	164 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](https://accessdata.fda.gov)

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