

K221182 Southern Transforaminal Lumbar Interbody Fusion (TLIF)Dec 8, 2022
227 days to decisionK221182 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k221182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 25, 2022
Decision date	Dec 8, 2022
Days to decision	227 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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221182/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026