

K253373 Southern Craniomaxillofacial (CMF) SystemDec 19, 2025
80 days to decisionK253373 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k253373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Sep 30, 2025
Decision date	Dec 19, 2025
Days to decision	80 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	Applied Technical Services (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/k253373/> 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 14, 2026