

K163366 Shanghai Sanyou CARMEN Cervical Fusion SystemOct 5, 2017
309 days to decisionK163366 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k163366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Nov 30, 2016
Decision date	Oct 5, 2017
Days to decision	309 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Sanyou Medical Co, Ltd.
Location	Bartlett, TN, US
Contact	David Fan
510(k) history	9 submissions · 9 cleared · 2013-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163366/> 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