

**K163422 Shanghai Sanyou PEEK Cage System**Sep 18, 2017  
286 days to decisionK163422 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k163422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 6, 2016
Decision date	Sep 18, 2017
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163422/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026