

K230872 Halis™ Lumbar Cage System, Lydia™ Anterior Lumbar Fusion System, Dica™ Direction Changeable Lumbar Cage System, KEYSTONE Cage SystemDec 12, 2023
257 days to decisionK230872 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k230872/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 30, 2023
Decision date	Dec 12, 2023
Days to decision	257 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/k230872/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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