

K232218 Zenius™ Spinal SystemAug 24, 2023
29 days to decisionK232218 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k232218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 26, 2023
Decision date	Aug 24, 2023
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medyssey USA, Inc.
Location	Apple Valley, MN, US
Contact	Youngsu Jang
510(k) history	19 submissions · 19 cleared · 2013-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232218/> 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 13, 2026