

**K181978 Zenius™, Iliad™ and Kora™ Spinal Fixation Systems**Aug 13, 2018  
20 days to decisionK181978 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k181978/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 24, 2018
Decision date	Aug 13, 2018
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medyssey USA, Inc.</b>
Location	Apple Valley, MN, US
Contact	Shawn Kim
510(k) history	19 submissions · 19 cleared · 2013-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181978/> 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