

K162134 ENNOVATE Spinal SystemDec 14, 2016
135 days to decisionK162134 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k162134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 1, 2016
Decision date	Dec 14, 2016
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap Implant Systems, LLC
Location	Center Valley, PA, US
Contact	Paul Amudala
510(k) history	22 submissions · 22 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162134/> 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 16, 2026