

K100147 S4 CERVICAL OCCIPITAL PLATE SPINAL SYSTEMJul 23, 2010
185 days to decisionK100147 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k100147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 19, 2010
Decision date	Jul 23, 2010
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap Implant System, Inc.
Location	Center Valley, PA, US
Contact	Lisa Boyle
510(k) history	18 submissions · 18 cleared · 2007-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100147/> 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 14, 2026