FDA 510(k) Premarket Notification

K083004 MILI (MINIMALLY INVASIVE LUMBAR IMPLANT) SYSTEM

CLEARED

Jul 2, 2009
267 days to decision

K083004 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k083004/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 8, 2008
Decision date	Jul 2, 2009
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap Implant Systems, Inc.**
Location	Center Valley, PA, US
Contact	Lisa Boyle
510(k) history	22 submissions · 22 cleared · 2007-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k083004/ 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 17, 2026