

K170611 SETx Pedicle Screw SystemMay 25, 2017
85 days to decisionK170611 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k170611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 1, 2017
Decision date	May 25, 2017
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xenco Medical, LLC
Location	San Diego, CA, US
Contact	Gustavo Prado
510(k) history	16 submissions · 16 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170611/> 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 26, 2026