

**K180626 Pedimax II - Pedicular Screw Spinal System**Feb 1, 2019  
329 days to decisionK180626 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k180626/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 9, 2018
Decision date	Feb 1, 2019
Days to decision	329 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gm Dos Reis Industria E Comercio Ltda.</b>
Location	Campinas, BR
Contact	Paula Oliveira
510(k) history	3 submissions · 3 cleared · 2019-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180626/> 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 27, 2026