FDA 510(k) Premarket Notification

K180626 Pedimax II - Pedicular Screw Spinal System

CLEARED

Feb 1, 2019
329 days to decision

K180626 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k180626/

SUBMISSION DETAILS

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

Company	**Gm Dos Reis Industria E Comerico Ltda.**
Location	Campinas, BR
Contact	Paula Oliveira
510(k) history	3 submissions · 3 cleared · 2019-2023