FDA 510(k) Premarket Notification

K152039 Genesys Spine TiLock2 Spinal System

CLEARED

Oct 28, 2015
98 days to decision

K152039 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k152039/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 22, 2015
Decision date	Oct 28, 2015
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Genesys Spine**
Location	Austin, TX, US
Contact	William W Sowers
510(k) history	31 submissions · 31 cleared · 2010-2025