FDA 510(k) Premarket Notification

K161032 neon3™ universal OCT spinal stabilization

CLEARED

Dec 22, 2016
253 days to decision

K161032 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k161032/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Apr 13, 2016
Decision date	Dec 22, 2016
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ulrich GmbH & Co. KG**
Location	Ulm, DE
Contact	Christoph Ulrich
510(k) history	24 submissions · 23 cleared · 2005-2025