FDA 510(k) Premarket Notification

K143471 VERTEX Reconstruction System

CLEARED

Feb 6, 2015
63 days to decision

K143471 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k143471/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Dec 5, 2014
Decision date	Feb 6, 2015
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek USA, Inc.**
Location	Memphis, TN, US
Contact	Lee Grant
510(k) history	170 submissions · 159 cleared · 2000-2026