FDA 510(k) Premarket Notification

K182182 YUKON OCT Spinal System

CLEARED

Nov 15, 2018
94 days to decision

K182182 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k182182/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Aug 13, 2018
Decision date	Nov 15, 2018
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**K2m**
Location	Leesburg, VA, US
Contact	Nancy Giezen
510(k) history	16 submissions · 16 cleared · 2014-2018