FDA 510(k) Premarket Notification

K170318 NeoFuse Ti3D PLIF/TLIF/Cervical Interbody

CLEARED

Jul 12, 2017
161 days to decision

K170318 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k170318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 1, 2017
Decision date	Jul 12, 2017
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ht Medical, LLC**
Location	Tulsa, OK, US
Contact	Robert Compton
510(k) history	3 submissions · 3 cleared · 2016-2017