FDA 510(k) Premarket Notification

K153615 NeoFuse HA Enhanced PLIF/TLIF

CLEARED

May 6, 2016
141 days to decision

K153615 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k153615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 17, 2015
Decision date	May 6, 2016
Days to decision	141 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