FDA 510(k) Premarket Notification

K170511 NeoFuse HA Enhanced PLIF/TLIF

CLEARED

Apr 25, 2017
63 days to decision

K170511 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k170511/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 21, 2017
Decision date	Apr 25, 2017
Days to decision	63 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