FDA 510(k) Premarket Notification

K190544 XIHPOS™ ZFUZE™ Interbody Fusion System

CLEARED

Nov 1, 2019
242 days to decision

K190544 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190544/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 4, 2019
Decision date	Nov 1, 2019
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Difusion Technologies**
Location	Austin, TX, US
Contact	Derrick Johns
510(k) history	3 submissions · 3 cleared · 2010-2019

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells**
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov