FDA 510(k) Premarket Notification

K201287 Impulse Interbody Fusion System

CLEARED

Dec 22, 2020
222 days to decision

K201287 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k201287/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 14, 2020
Decision date	Dec 22, 2020
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Degen Medical**
Location	Florence, SC, US
Contact	Craig Black
510(k) history	16 submissions · 16 cleared · 2015-2025