FDA 510(k) Premarket Notification

CLEARED

K201267 Adaptix Interbody System with Titan nanoLOCK Surface Technology

Aug 26, 2020
106 days to decision

K201267 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k201267/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 12, 2020
Decision date	Aug 26, 2020
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek**
Location	Memphis, TN, US
Contact	Diamond Wallace
510(k) history	154 submissions · 147 cleared · 2002-2021