FDA 510(k) Premarket Notification

K203003 Pantheon IBFD

CLEARED

Jul 7, 2021
279 days to decision

K203003 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k203003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 1, 2020
Decision date	Jul 7, 2021
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pantheon Spinal**
Location	Austin, TX, US
Contact	Dave Lamb
510(k) history	4 submissions · 4 cleared · 2013-2024