FDA 510(k) Premarket Notification

CLEARED

K180373 CancelleX Porous Titanium Lumbar Interbody Device

Aug 24, 2018
193 days to decision

K180373 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k180373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 12, 2018
Decision date	Aug 24, 2018
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Xenco Medical, LLC**
Location	San Diego, CA, US
Contact	Gustavo R. Prado
510(k) history	16 submissions · 16 cleared · 2014-2025