FDA 510(k) Premarket Notification

K182284 Tyber Medical PT Interbody Spacer

CLEARED

Jan 18, 2019
148 days to decision

K182284 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k182284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 23, 2018
Decision date	Jan 18, 2019
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tyber Medical, LLC**
Location	Morristown, NJ, US
Contact	Mark F. Schenk
Website	https://www.tybermed.com
510(k) history	29 submissions · 29 cleared · 2013-2026