

K182284 Tyber Medical PT Interbody SpacerJan 18, 2019
148 days to decisionK182284 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182284/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026