FDA 510(k) Premarket Notification

K183064 TxTi IBF System

CLEARED

Jun 28, 2019
235 days to decision

K183064 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k183064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 5, 2018
Decision date	Jun 28, 2019
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Innovasis, Inc.**
Location	Salt Lake City, UT, US
Contact	Marshall McCarty
510(k) history	33 submissions · 32 cleared · 2004-2025