FDA 510(k) Premarket Notification

K190684 LxHA PEEK Lateral IBF System

CLEARED

Jun 17, 2019
91 days to decision

K190684 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 18, 2019
Decision date	Jun 17, 2019
Days to decision	91 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