FDA 510(k) Premarket Notification

K190216 SpaceFlex Knee

CLEARED

Jun 9, 2019
125 days to decision

K190216 · Product code: **MBB** · Orthopedic
Source: https://www.510kdatabase.net/k190216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Feb 4, 2019
Decision date	Jun 9, 2019
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**G21, S.R.L.**
Location	San Possidonio, IT
Contact	Filippo Foroni
510(k) history	12 submissions · 12 cleared · 2015-2025