FDA 510(k) Premarket Notification

K190181 Instruments for LINK MEGASYSTEM-C Family

CLEARED

Oct 25, 2019
266 days to decision

K190181 · Product code: **KRO** · Orthopedic
Source: https://www.510kdatabase.net/k190181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Feb 1, 2019
Decision date	Oct 25, 2019
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**LinkBio Corp.**
Location	Rockaway, NJ, US
Contact	Terry Powell
510(k) history	2 submissions · 2 cleared · 2019-2025