FDA 510(k) Premarket Notification

K191779 Attune Revision LPS Inserts

CLEARED

Oct 8, 2019
98 days to decision

K191779 · Product code: **KRO** · Orthopedic
Source: https://www.510kdatabase.net/k191779/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Jul 2, 2019
Decision date	Oct 8, 2019
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy(Ireland)**
Location	Cork, IE
Contact	Kathy Harris
510(k) history	13 submissions · 13 cleared · 2010-2022