FDA 510(k) Premarket Notification

K221697 INJECTION PIN (KIP(02031-02061) (03031-03061))

CLEARED

Mar 3, 2023
266 days to decision

K221697 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k221697/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 10, 2022
Decision date	Mar 3, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Slk Ortho, LLC**
Location	Long Grove, IL, US
Contact	Lawrence Kluge
510(k) history	1 submissions · 1 cleared · 2023-2023