FDA 510(k) Premarket Notification

K221245 PTA Balloon Dilatation Catheter

CLEARED

Dec 14, 2022
226 days to decision

K221245 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k221245/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 2, 2022
Decision date	Dec 14, 2022
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kossel Medtech (Suzhou) Co., Ltd.**
Location	Suzhou, CN
Contact	Ron Lv
510(k) history	5 submissions · 5 cleared · 2018-2023