FDA 510(k) Premarket Notification

K222705 Introducer Needle

CLEARED

May 22, 2023
257 days to decision

K222705 · Product code: **LJE** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Sep 7, 2022
Decision date	May 22, 2023
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Youcare Technology Co.,Ltd. (Wuhan)**
Location	Wuhan, CN
Contact	Bing Hu
510(k) history	2 submissions · 2 cleared · 2023-2023