FDA 510(k) Premarket Notification

K210464 Auto Disable Syringe

CLEARED

Aug 24, 2021
189 days to decision

K210464 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k210464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Feb 16, 2021
Decision date	Aug 24, 2021
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anhui Tiankang Medical Technology Co., Ltd.**
Location	Tianchang, CN
Contact	Bai Baodong
510(k) history	12 submissions · 12 cleared · 2019-2023