FDA 510(k) Premarket Notification

K191644 TK Safety Needle

CLEARED

Aug 6, 2020
414 days to decision

K191644 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k191644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 19, 2019
Decision date	Aug 6, 2020
Days to decision	414 days
Third-party review	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