FDA 510(k) Premarket Notification

CLEARED

K212518 Jeesung Safety Syringe and Single Use Needles

Aug 18, 2022
373 days to decision

K212518 · Product code: **MEG** · General Hospital
Source: https://www.510kdatabase.net/k212518/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Antistick (MEG)
Date received	Aug 10, 2021
Decision date	Aug 18, 2022
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jeesung Medical Co., Ltd.**
Location	Daejeon, KR
Contact	Choi Yong Hyun
510(k) history	3 submissions · 3 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	**Plusglobal**
Contact	Peter Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov