FDA 510(k) Premarket Notification

K231707 ResQ Administration Set

CLEARED

Jan 3, 2024
205 days to decision

K231707 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k231707/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jun 12, 2023
Decision date	Jan 3, 2024
Days to decision	205 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Q For Plastic Industries**
Location	Badr, EG
Contact	Islam Nazieh Mohamed Ali
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Global Quality and Regulatory Services**
Contact	Abdel B Halim

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