FDA 510(k) Premarket Notification

K180739 Clearlink System Solution Set

CLEARED

May 28, 2019
432 days to decision

K180739 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k180739/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 22, 2018
Decision date	May 28, 2019
Days to decision	432 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corporation**
Location	Round Lake, IL, US
Contact	Jeanette Licata
510(k) history	61 submissions · 60 cleared · 2004-2025