FDA 510(k) Premarket Notification

K211078 Progreat Lambda

CLEARED

Dec 21, 2021
253 days to decision

K211078 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k211078/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Apr 12, 2021
Decision date	Dec 21, 2021
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Clinical Supply Co., Ltd.**
Location	Kakamigahara, JP
Contact	Vaibhav Sivaramakrishan
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Terumo Medical Corporation**
Contact	Vaibhav Sivaramakrishan

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