

**K211078 Progreat Lambda**Dec 21, 2021  
253 days to decisionK211078 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211078/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Terumo Medical Corporation</b>
Contact	Vaibhav Sivaramakrishan

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211078/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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