

K242453 Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2)Dec 12, 2024
115 days to decisionK242453 · Product code: FRC · General Hospital
Source: <https://www.510kdatabase.net/k242453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Aug 19, 2024
Decision date	Dec 12, 2024
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C)

APPLICANT

Company	Terragene S.A.
Location	Rosario, AR
Contact	Hernando Carrizo
510(k) history	8 submissions · 7 cleared · 2017-2024

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