

K232103 Terragene® Chemdye® Multivariable Chemical Indicator (CD40), Terragene® Chemdye® Chemical Process Indicator (CD42), Terragene® Cintape® Chemical Process Indicator Tape (CT40)Apr 5, 2024
266 days to decisionK232103 · Product code: **QKM** · General Hospital
Source: <https://www.510kdatabase.net/k232103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	A Chemical Vapor Sterilization Multivariable Chemical Indicator (QKM)
Date received	Jul 14, 2023
Decision date	Apr 5, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Licensale, Inc.
Contact	Raymond Kelly

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

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