

K213280 BD Kiestra Methicillin-resistant Staphylococcus aureus (MRSA) Application, BD Kiestra MRSA AppMay 4, 2023
580 days to decisionK213280 · Product code: **QQY** · Microbiology
Source: <https://www.510kdatabase.net/k213280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Plate Imaging System For Qualitative Assessment Of Resistant Organisms (QQY)
Date received	Oct 1, 2021
Decision date	May 4, 2023
Days to decision	580 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bd Kiestra B.V.
Location	Drachten, NL
Contact	Karin Brands
510(k) history	1 submissions · 1 cleared · 2023-2023

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