

K212068 Biotech Dental KitsNov 8, 2021
129 days to decisionK212068 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k212068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Jul 2, 2021
Decision date	Nov 8, 2021
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biotech Dental, Sas
Location	Salon De Provence, FR
Contact	Delphine Mercier
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Melissa Burbage

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

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