

K213907 CareGUARD Sterilization WrapMar 14, 2022
90 days to decisionK213907 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k213907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Dec 14, 2021
Decision date	Mar 14, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Care Essentials Pty, Ltd.
Location	Parkside, South Australia, AU
Contact	Abhay Sinha
510(k) history	4 submissions · 4 cleared · 2014-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213907/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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