

K163144 gke Steri-Record Steam Mini-Bio-Plus self-contained biological indicator (SCBI)

Apr 7, 2017
149 days to decision

K163144 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k163144/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Nov 9, 2016
Decision date	Apr 7, 2017
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gke-GmbH
Location	Waldems, DE
Contact	Ulrich Kaiser
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163144/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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