

K201927 Getinge GSS610N Series Steam SterilizerMar 1, 2021
234 days to decisionK201927 · Product code: **FLE** · General Hospital
Source: <https://www.510kdatabase.net/k201927/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Jul 10, 2020
Decision date	Mar 1, 2021
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maquet GmbH
Location	Rastatt, DE
Contact	Holger Ullrich
Website	http://www.maquet.com/
510(k) history	3 submissions · 3 cleared · 2018-2022

Maquet GmbH is a global medical device manufacturer with a manufacturing facility in Rastatt, Germany. The company specializes in General Hospital devices, serving healthcare facilities worldwide. Maquet GmbH has received FDA 510(k) clearances from total submissions. All submissions focused on General Hospital devices. The company's regulatory activity spans from 2018 to 2022, with no recent submissions on record. The company's cleared devices include steam sterilization systems designed for hospital use. These products represent core technologies in sterile reprocessing ...

REGULATORY CONSULTANT

Consulting firm	Getinge
Contact	Mark Smith

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