

**K172159 Getinge GSS67N Series Steam Sterilizer**Jan 30, 2018  
196 days to decisionK172159 · Product code: **FLE** · General Hospital  
Source: <https://www.510kdatabase.net/k172159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Jul 18, 2017
Decision date	Jan 30, 2018
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maquet GmbH</b>
Location	Rastatt, DE
Contact	Holger Ullrich
Website	<a href="http://www.maquet.com/">http://www.maquet.com/</a>
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 ...

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