FDA 510(k) Premarket Notification

CLEARED

K214120 GSS610N21 Series Steam Sterilizer

May 18, 2022
139 days to decision

K214120 · Product code: **FLE** · General Hospital
Source: https://www.510kdatabase.net/k214120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Dec 30, 2021
Decision date	May 18, 2022
Days to decision	139 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	Barb Smith

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