

K242795 Getinge Assured MI Steam Migrating IntegratorOct 15, 2024
29 days to decisionK242795 · Product code: **JOJ** · General Hospital
Source: <https://www.510kdatabase.net/k242795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	Sep 16, 2024
Decision date	Oct 15, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Steritec Products Mfg. (A Getinge Group Company)
Location	Engelwood, CO, US
Contact	Muha Chris
510(k) history	1 submissions · 1 cleared · 2024-2024

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](https://accessdata.fda.gov)

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