

K190027 SteriStayMay 10, 2019
123 days to decisionK190027 · Product code: **ORC** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air Filter Portable Apparatus (ORC)
Date received	Jan 7, 2019
Decision date	May 10, 2019
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Toul Meditech AB
Location	V?ster?s, SE
Contact	Tomas Hansson
510(k) history	3 submissions · 3 cleared · 2016-2019

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