

K163455 SurgiCubeSep 28, 2017
293 days to decisionK163455 · Product code: **ORC** · General Hospital
Source: <https://www.510kdatabase.net/k163455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air Filter Portable Apparatus (ORC)
Date received	Dec 9, 2016
Decision date	Sep 28, 2017
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Surgicube International B.V.
Location	Vierpolders, NL
Contact	GER VIJFVINKEL
510(k) history	1 submissions · 1 cleared · 2017-2017

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