

**K153498 Operio**

Jul 20, 2016  
226 days to decision

K153498 · Product code: **ORC** · General Hospital  
Source: <https://www.510kdatabase.net/k153498/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air Filter Portable Apparatus (ORC)
Date received	Dec 7, 2015
Decision date	Jul 20, 2016
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k153498/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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