

**K173349 Operio**Dec 20, 2017  
56 days to decisionK173349 · Product code: **ORC** · General Hospital  
Source: <https://www.510kdatabase.net/k173349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air Filter Portable Apparatus (ORC)
Date received	Oct 25, 2017
Decision date	Dec 20, 2017
Days to decision	56 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/k173349/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026