

**K191967 Unyvero LRT BAL Application**Dec 20, 2019  
150 days to decisionK191967 · Product code: **QBH** · Microbiology  
Source: <https://www.510kdatabase.net/k191967/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lower Respiratory Microbial Nucleic Acid Detection System (QBH)
Date received	Jul 23, 2019
Decision date	Dec 20, 2019
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Curetis GmbH</b>
Location	Holzgerlingen, DE
Contact	Karsten Mueller
510(k) history	2 submissions · 1 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Radcliffe Consulting, Inc.</b>
Contact	Gail Radcliffe

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191967/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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