

**K200132 Ashvins**Feb 18, 2020  
28 days to decisionK200132 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k200132/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 21, 2020
Decision date	Feb 18, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicalcommunications GmbH</b>
Location	Heidelberg, DE
Contact	Martin Schinkmann
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Orasi Consulting, LLC</b>
Contact	Lena Sattler

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/k200132/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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