

**K212321 JiveX (Model Number / Release: 5.3)**Sep 23, 2021  
59 days to decisionK212321 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k212321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 26, 2021
Decision date	Sep 23, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Visus Health IT GmbH</b>
Location	Bochum, DE
Contact	Axel Schreiber
510(k) history	4 submissions · 4 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212321/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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