

K213637 JAZZ Solo sensorDec 10, 2021
22 days to decisionK213637 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k213637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Nov 18, 2021
Decision date	Dec 10, 2021
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jazz Imaging, LLC Db a Jazz Imaging
Location	San Jose, CA, US
Contact	Todd C Miller
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	W. Edward Johansen
Contact	Ed Johansen

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

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