

**K221955 Brasseler GEM, Brasseler GEM10, Brasseler GEM15,
Brasseler GEM20**Aug 31, 2022
57 days to decisionK221955 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k221955/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jul 5, 2022
Decision date	Aug 31, 2022
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Realcloud Imaging Inc. Db a Realcloud Imaging
Location	Ames, IA, US
Contact	Douglas A Golay
510(k) history	1 submissions · 1 cleared · 2022-2022

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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