

K221000 ON3DMay 23, 2022
49 days to decisionK221000 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k221000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 4, 2022
Decision date	May 23, 2022
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3D Ons, Inc.
Location	Gangnam-Gu, KR
Contact	Jeong Rae Cho
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	DongHa Lee

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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