

K200078 VARO PlanApr 10, 2020
87 days to decisionK200078 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k200078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 14, 2020
Decision date	Apr 10, 2020
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3D Industrial Imaging Co., Ltd.
Location	Gwanak-Gu, KR
Contact	Myungsuk Park
510(k) history	4 submissions · 4 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	Wise Company, Inc.
Contact	Sanglok Lee

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