

**K211480 NubeX**Jul 8, 2021  
57 days to decisionK211480 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k211480/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 12, 2021
Decision date	Jul 8, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Techheim Co., Ltd.</b>
Location	Seoul, KR
Contact	Weon Yong Lee
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>KMC, Inc.</b>
Contact	JeongKeun Kim

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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