

**K253446 AeroDR TX c02**Apr 10, 2026  
190 days to decisionK253446 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k253446/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Oct 2, 2025
Decision date	Apr 10, 2026
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dk Medical Systems Co., Ltd.</b>
Location	Pyeongtaek-Si, KR
Contact	Young Woo Kang
510(k) history	3 submissions · 3 cleared · 2025-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>KMC, Inc.</b>
Contact	Dong Ha 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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