

**K250170 PHAROS**Aug 15, 2025  
206 days to decisionK250170 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k250170/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Jan 21, 2025
Decision date	Aug 15, 2025
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brightonix Imaging</b>
Location	Seoul, KR
Contact	Radcheck Yang
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>510K FDA, Inc.</b>
Contact	Lee Strong

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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