FDA 510(k) Premarket Notification

K250170 PHAROS

CLEARED

Aug 15, 2025
206 days to decision

K250170 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k250170/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**510K FDA, Inc.**
Contact	Lee Strong

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