

K240827 SET-5002May 24, 2024
59 days to decisionK240827 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k240827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Mar 26, 2024
Decision date	May 24, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shimadzu Corporation Medical Systems Division
Location	Kyoto, JP
Contact	Koichi Kataoka
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
Contact	Daniel Kamm

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