

K242994 OncoStudio (OS-01)Feb 24, 2025
151 days to decisionK242994 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k242994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Sep 26, 2024
Decision date	Feb 24, 2025
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oncosoft. Co., Ltd.
Location	Seoul, KR
Contact	Boram Kim
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242994/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026