

K260964 NanoZoomer S540MD Slide Scanner System

Jul 22, 2026
121 days to decision

K260964 · Product code: **PSY** · Pathology
Source: <https://www.510kdatabase.net/k260964/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Whole Slide Imaging System (PSY)
Date received	Mar 23, 2026
Decision date	Jul 22, 2026
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hamamatsu Photonics K.K.
Location	Bridgewater, NJ, US
Contact	Shinichi Fujisaka
510(k) history	10 submissions · 10 cleared · 1989-2026