

K233027 NanoZoomer S360MD Slide scanner systemDec 22, 2023
88 days to decisionK233027 · Product code: **PSY** · Pathology
Source: <https://www.510kdatabase.net/k233027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Whole Slide Imaging System (PSY)
Date received	Sep 25, 2023
Decision date	Dec 22, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Hamamatsu Photonics K.K.
Location	Bridgewater, NJ, US
Contact	Shinichi Fujisaka
510(k) history	8 submissions · 8 cleared · 1989-2023

REGULATORY CONSULTANT

Consulting firm	Hyman, Phelps & McNamara, P.C.
Contact	Adrienne Lenz

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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