

**K213883 NanoZoomer S360MD Slide scanner system**Sep 27, 2022  
288 days to decisionK213883 · Product code: **PSY** · Pathology  
Source: <https://www.510kdatabase.net/k213883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Slide Imaging System (PSY)
Date received	Dec 13, 2021
Decision date	Sep 27, 2022
Days to decision	288 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hyman, Phelps &amp; McNamara, P.C.</b>
Contact	Jeffrey Gibbs

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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