

K232208 Sectra Digital Pathology Module (Version 3.3)Apr 16, 2024
265 days to decisionK232208 · Product code: **PSY** · Pathology
Source: <https://www.510kdatabase.net/k232208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Slide Imaging System (PSY)
Date received	Jul 26, 2023
Decision date	Apr 16, 2024
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sectra AB
Location	Aubrey, TX, US
Contact	Edoardo Mastrovito
510(k) history	5 submissions · 5 cleared · 2000-2024

REGULATORY CONSULTANT

Consulting firm	Medical Device Regulatory Services
Contact	Peter Altman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232208/> 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 13, 2026