FDA 510(k) Premarket Notification

K232208 Sectra Digital Pathology Module (Version 3.3)

CLEARED

Apr 16, 2024
265 days to decision

K232208 · 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