FDA 510(k) Premarket Notification

K230839 Concentriq Dx

CLEARED

Feb 8, 2024
318 days to decision

K230839 · Product code: **PSY** · Pathology
Source: https://www.510kdatabase.net/k230839/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Slide Imaging System (PSY)
Date received	Mar 27, 2023
Decision date	Feb 8, 2024
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Proscia, Inc.**
Location	Philadelphia, PA, US
Contact	Kim Rendon
510(k) history	1 submissions · 1 cleared · 2024-2024