FDA 510(k) Premarket Notification

K232088 Altris IMS

CLEARED

Jul 31, 2023
18 days to decision

K232088 · Product code: **NFJ** · Ophthalmic
Source: https://www.510kdatabase.net/k232088/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Jul 13, 2023
Decision date	Jul 31, 2023
Days to decision	18 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Altris, Inc.**
Location	Chicago, IL, US
Contact	Andrew Kuropyatnyk
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov