FDA 510(k) Premarket Notification

K200422 Image Quality Analyzer (IQA)

CLEARED

Dec 24, 2020
308 days to decision

K200422 · Product code: **NFJ** · Ophthalmic
Source: https://www.510kdatabase.net/k200422/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Feb 20, 2020
Decision date	Dec 24, 2020
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visionquest Biomedical, Inc.**
Location	Albuquerque, NM, US
Contact	Gilberto Zamora
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Ora**
Contact	Ryan Bouchard

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