FDA 510(k) Premarket Notification

K220956 Libby Echo:Prio

CLEARED

Jul 20, 2022
110 days to decision

K220956 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k220956/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 1, 2022
Decision date	Jul 20, 2022
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dyad Medical, Inc.**
Location	Boston, MA, US
Contact	Ronny Shalev
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Pharmalex Pty, Ltd.**
Contact	Yervant Chijian

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