FDA 510(k) Premarket Notification

K240943 LungVision

CLEARED

Oct 1, 2024
179 days to decision

K240943 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k240943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 5, 2024
Decision date	Oct 1, 2024
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bodyvision Medical , Ltd.**
Location	Ramat Hasharon, IL
Contact	Benny Krauz
510(k) history	4 submissions · 4 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

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