FDA 510(k) Premarket Notification

K240786 AutoChamber

CLEARED

Oct 10, 2024
202 days to decision

K240786 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k240786/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 22, 2024
Decision date	Oct 10, 2024
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**HeartLung Corporation**
Location	Torrance, CA, US
Contact	Mark Scott
510(k) history	3 submissions · 3 cleared · 2022-2025