FDA 510(k) Premarket Notification

K231683 inHEART Models

CLEARED

Feb 29, 2024
265 days to decision

K231683 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k231683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 9, 2023
Decision date	Feb 29, 2024
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inheart, Sas**
Location	Pessac, FR
Contact	Audrey Labeque
510(k) history	2 submissions · 2 cleared · 2022-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k231683/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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