

K242807 HeartFocus (V.1.1.1)Apr 4, 2025
199 days to decisionK242807 · Product code: **QJU** · Radiology
Source: <https://www.510kdatabase.net/k242807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Acquisition And/or Optimization Guided By Artificial Intelligence (QJU)
Date received	Sep 17, 2024
Decision date	Apr 4, 2025
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Deski
Location	Bordeaux, FR
Contact	Saray Ugidos Seman
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242807/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026