

**K260780 HeartFocus**Jun 3, 2026  
85 days to decisionK260780 · Product code: **QJU** · Radiology  
Source: <https://www.510kdatabase.net/k260780/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Image Acquisition And/or Optimization Guided By Artificial Intelligence (QJU)
Date received	Mar 10, 2026
Decision date	Jun 3, 2026
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Deski</b>
Location	Bordeaux, FR
Contact	Kelly Porfirio
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260780/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026