

K212233 RTHawk, HeartVista Cardiac PackageOct 5, 2021
81 days to decisionK212233 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k212233/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 16, 2021
Decision date	Oct 5, 2021
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heartvista, Inc.
Location	Menlo Park, CA, US
Contact	James J Rogers
Website	http://www.heartvista.com/
510(k) history	6 submissions · 6 cleared · 2014-2021

Heartvista, Inc. develops intelligent software to streamline MRI examinations. The company specializes in Radiology devices, with a focus on automating cardiac MRI acquisition. Heartvista's technology enables clinicians to perform accurate, high-quality scans consistently and rapidly. Heartvista received FDA 510(k) clearances from total submissions between 2014 and 2021. All submissions were in the Radiology category. The company's cleared devices include the RTHawk and RTHawk Workstation platforms, which automate cardiac imaging workflows. Heartvista has been inactive si...