FDA 510(k) Premarket Notification

CLEARED

K170090 RTHawk, HeartVista Cardiac Package

Jul 14, 2017
185 days to decision

K170090 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k170090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jan 10, 2017
Decision date	Jul 14, 2017
Days to decision	185 days
Third-party review	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...