

**K133848 RTHAWK, RTHAWK, OR HEARTVISTA WORKSTATION  
WITH RTHAWK**Jun 25, 2014  
189 days to decisionK133848 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k133848/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Dec 18, 2013
Decision date	Jun 25, 2014
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Heartvista, Inc.</b>
Location	Menlo Park, CA, US
Contact	JAMES J ROGERS
Website	<a href="http://www.heartvista.com/">http://www.heartvista.com/</a>
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...