

K153740 RTHawk, HeartVista Cardiac PackageJun 30, 2016
185 days to decisionK153740 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k153740/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received | Dec 28, 2015 |
| Decision date | Jun 30, 2016 |
| 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...