

**K211406 OASIS MRI System**Oct 7, 2021  
154 days to decisionK211406 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k211406/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	May 6, 2021
Decision date	Oct 7, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hitachi Healthcare Americas</b>
Location	Twinsburg, OH, US
Contact	Aaron Pierce
510(k) history	12 submissions · 12 cleared · 2018-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>FUJIFILM Healthcare Americas Corporation</b>
Contact	Aaron Pierce

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211406/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026