

**K211432 Myomics Q**Nov 23, 2021  
200 days to decisionK211432 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k211432/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 7, 2021
Decision date	Nov 23, 2021
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Phantomics, Inc.</b>
Location	Seoul, KR
Contact	Sangmin Cho
510(k) history	2 submissions · 2 cleared · 2021-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>KMC, Inc.</b>
Contact	Milly Milly

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/k211432/> 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 26, 2026