

K203249 Nucleus.ioDec 4, 2020
30 days to decisionK203249 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k203249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 4, 2020
Decision date	Dec 4, 2020
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nucleushealth, LLC
Location	San Diego, CA, US
Contact	Zachary Wright
510(k) history	2 submissions · 2 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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