

K233660 nCommand Lite SystemMar 18, 2024
124 days to decisionK233660 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k233660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 15, 2023
Decision date	Mar 18, 2024
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ionic Health
Location	S?o Jos? Dos Campos/Sp, BR
Contact	Jose Leovigildo de Melo Coelho Filho
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	The FDA Group, LLC
Contact	Jay Mansour

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

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