

**K223841 KBA3D**May 30, 2023  
159 days to decisionK223841 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k223841/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 22, 2022
Decision date	May 30, 2023
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>S.M.A.I.O</b>
Location	Saint-Priest, FR
Contact	Jean-Charles Roussouly
510(k) history	10 submissions · 10 cleared · 2020-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>BioVera, Inc.</b>
Contact	Robert A Poggie

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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