FDA 510(k) Premarket Notification

K223841 KBA3D

CLEARED

May 30, 2023
159 days to decision

K223841 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k223841/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A Poggie

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