FDA 510(k) Premarket Notification

K223660 SaintView

CLEARED

Aug 14, 2023
251 days to decision

K223660 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k223660/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 6, 2022
Decision date	Aug 14, 2023
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inviz Corporation**
Location	Gwangju, KR
Contact	Priscilla Chung
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

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