FDA 510(k) Premarket Notification

K212896 Visible Patient Suite

CLEARED

Nov 5, 2021
56 days to decision

K212896 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k212896/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 10, 2021
Decision date	Nov 5, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visible Patient, Sas**
Location	Strasbourg, FR
Contact	Emeline Degivry
510(k) history	2 submissions · 2 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J Smith

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

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Device record: https://www.510kdatabase.net/k212896/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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