

K212230 TruSPECT Radiological Image Processing StationAug 16, 2021
31 days to decisionK212230 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k212230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 16, 2021
Decision date	Aug 16, 2021
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spectrum Dynamics Medical, Ltd.
Location	North Industrial Park. Caesarea, IL
Contact	Igor Naroditsky
510(k) history	8 submissions · 8 cleared · 2016-2026

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