

K211655 aPROMISEJul 27, 2021
60 days to decisionK211655 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k211655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 28, 2021
Decision date	Jul 27, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exini Diagnostics AB
Location	Indianapolis, IN, US
Contact	Aseem Anand
510(k) history	4 submissions · 4 cleared · 2012-2022

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group
Contact	Donna-Bea Tillman

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211655/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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