

**K220590 aPROMISE X**Apr 29, 2022  
59 days to decisionK220590 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k220590/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 1, 2022
Decision date	Apr 29, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biologics Consulting Group</b>
Contact	Donna-Bea Tillman

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220590/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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