

**K230023 ART-Plan**Apr 19, 2023  
105 days to decisionK230023 · Product code: **QKB** · Radiology  
Source: <https://www.510kdatabase.net/k230023/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Jan 4, 2023
Decision date	Apr 19, 2023
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Therapanacea Sas</b>
Location	Paris, FR
Contact	Catherine Martineau-Huynh
510(k) history	4 submissions · 4 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230023/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026