

**K223758 Epione**May 3, 2023  
139 days to decisionK223758 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k223758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Dec 15, 2022
Decision date	May 3, 2023
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quantum Surgical Sas</b>
Location	Montpellier, FR
Contact	Elise Lagacherie
510(k) history	2 submissions · 2 cleared · 2022-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223758/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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