

K211645 EpioneFeb 24, 2022
272 days to decisionK211645 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k211645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 28, 2021
Decision date	Feb 24, 2022
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

CLINICAL EVIDENCE - NCT04230642

Multicenter Study to Evaluate a New Robotic Device for Image-guided Percutaneous Needle Placement

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	22 patients (actual)
Study sites	2 sites
Condition studied	Hepatic Tumor
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 2, 2021
Sponsor	Quantum Surgical (Industry)

Primary outcome

Evaluation of the safety related to the procedure

Secondary outcome

Evaluation of the accuracy of the device

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04230642