

K213759 XACT Robotic System, ACE ModelSep 23, 2022
297 days to decisionK213759 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k213759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 30, 2021
Decision date	Sep 23, 2022
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xact Robotics, Ltd.
Location	Caesarea, IL
Contact	Dan Sigal
510(k) history	4 submissions · 4 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan S Kahan

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

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