

K221116 XACT ACE Robotic SystemMay 13, 2022
28 days to decisionK221116 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k221116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 15, 2022
Decision date	May 13, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xact Robotics, Ltd.
Location	Caesarea, IL
Contact	Chen Levin
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](https://accessdata.fda.gov)

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