

**K071378 MODIFICATION TO EMPOWER CT/CTA INJECTOR
SYSTEM, MODELS 9800/9900 PRODUCT SERIES**Jun 13, 2007
27 days to decisionK071378 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k071378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 17, 2007
Decision date	Jun 13, 2007
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	E-Z-Em, Inc.
Location	Mchenry, IL, US
Contact	STEVEN HARTMAN
510(k) history	56 submissions · 56 cleared · 1977-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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