

K031571 EMPOWERCTA INJECTOR SYSTEM, MODELS 9930 & 9910 & 9825

Jun 19, 2003
30 days to decision

K031571 · Product code: **IZQ** · Radiology
Source: <https://www.510kdatabase.net/k031571/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	May 20, 2003
Decision date	Jun 19, 2003
Days to decision	30 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.net

Device record: <https://www.510kdatabase.net/k031571/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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