

**K090296 ATOMLAB 400 AND ATOMLAB 500 DOSE
CALIBRATORS, MODELS 086-330, -331, -332, -335 AND -336**Feb 19, 2009
13 days to decisionK090296 · Product code: **KPT** · Radiology
Source: <https://www.510kdatabase.net/k090296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Dose, Radionuclide (KPT)
Date received	Feb 6, 2009
Decision date	Feb 19, 2009
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Biodex Medical Systems, Inc.
Location	Shirley, NY, US
Contact	CLYDE SCHLEIN
510(k) history	9 submissions · 8 cleared · 1994-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090296/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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