

K023860 MICROALBUMIN REAGENT SET AND CALIBRATORSApr 28, 2003
159 days to decisionK023860 · Product code: **DDZ** · Chemistry
Source: <https://www.510kdatabase.net/k023860/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Albumin, Fitc, Antigen, Antiserum, Control (DDZ) |
| Date received | Nov 20, 2002 |
| Decision date | Apr 28, 2003 |
| Days to decision | 159 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Pointe Scientific, Inc., |
| Location | Mchenry, IL, US |
| Contact | RON JAMISON |
| 510(k) history | 74 submissions · 74 cleared · 1981-2007 |

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