

K062118 POINTE 360Jul 13, 2007
353 days to decisionK062118 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k062118/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hexokinase, Glucose (CFR) |
| Date received | Jul 25, 2006 |
| Decision date | Jul 13, 2007 |
| Days to decision | 353 days |
| Third-party review | No |
| Summary / Statement | Summary |

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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