

K093297 EPOC BGEM, EPOC READER, EPOC HOST, EPOC CARE-FILL CAPILLARY TUBEJun 9, 2010
231 days to decisionK093297 · Product code: **KHP** · Chemistry
Source: <https://www.510kdatabase.net/k093297/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Acid, Lactic, Enzymatic Method (KHP) |
| Date received | Oct 21, 2009 |
| Decision date | Jun 9, 2010 |
| Days to decision | 231 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Epocal, Inc. |
| Location | Ottawa, CA |
| Contact | ROY LAYER |
| 510(k) history | 7 submissions · 7 cleared · 2006-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093297/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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