

**K042193 DIAZYME GLYCATED SERUM PROTEIN ENZYMATIC
ASSAY KIT**Oct 29, 2004
78 days to decisionK042193 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k042193/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Assay, Glycosylated Hemoglobin (LCP) |
| Date received | Aug 12, 2004 |
| Decision date | Oct 29, 2004 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Diazyme Laboratories |
| Location | Irvine, CA, US |
| Contact | CHONG YUAN |
| 510(k) history | 41 submissions · 41 cleared · 2003-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042193/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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