

K103557 DIAZYME HS CRP ASSAY KIT / CALIBRATOR SET / CONTROL SETApr 27, 2011
146 days to decisionK103557 · Product code: **DCK** · Chemistry
Source: <https://www.510kdatabase.net/k103557/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | C-reactive Protein, Antigen, Antiserum, And Control (DCK) |
| Date received | Dec 2, 2010 |
| Decision date | Apr 27, 2011 |
| Days to decision | 146 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103557/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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