

K063804 OLYMPUS TRIGLYCERIDE TEST SYSTEMMar 23, 2007
91 days to decisionK063804 · Product code: **CDT** · Chemistry
Source: <https://www.510kdatabase.net/k063804/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT) |
| Date received | Dec 22, 2006 |
| Decision date | Mar 23, 2007 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Olympus America, Inc. |
| Location | Lake Success, NY, US |
| Contact | BEV HARDING |
| 510(k) history | 149 submissions · 149 cleared · 1994-2012 |

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