

**K071255 ZYMUTEST HIA IGGAM, ZYMUTEST IGG, MODEL
RK040D, RK040A**Sep 7, 2007
126 days to decisionK071255 · Product code: **LCO** · Hematology
Source: <https://www.510kdatabase.net/k071255/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Platelet Factor 4 Radioimmunoassay (LCO) |
| Date received | May 4, 2007 |
| Decision date | Sep 7, 2007 |
| Days to decision | 126 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Hyphen Biomed |
| Location | Mason, OH, US |
| Contact | OLA ANDERSON |
| 510(k) history | 6 submissions · 6 cleared · 2005-2007 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071255/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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