

K040198 LABONE COCAINE METABOLITE MICRO-PLATE EIAMar 5, 2004
36 days to decisionK040198 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k040198/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO) |
| Date received | Jan 29, 2004 |
| Decision date | Mar 5, 2004 |
| Days to decision | 36 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Labone, Inc. |
| Location | Lenexa, KS, US |
| Contact | LIUMING YU |
| 510(k) history | 2 submissions · 2 cleared · 2004-2004 |

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