

K031052 CARESTART HCG ONE-STEP PREGNANCY TESTJun 13, 2003
72 days to decisionK031052 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k031052/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Human Chorionic Gonadotropin (DHA) |
| Date received | Apr 2, 2003 |
| Decision date | Jun 13, 2003 |
| Days to decision | 72 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Access Bio Incorporate |
| Location | North Brunswick, NJ, US |
| Contact | YOUNG HO CHOI |
| 510(k) history | 4 submissions · 4 cleared · 2003-2005 |

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