

K011478 I-STAT SYSTEMJul 2, 2001
49 days to decisionK011478 · Product code: **KHP** · Chemistry
Source: <https://www.510kdatabase.net/k011478/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Acid, Lactic, Enzymatic Method (KHP) |
| Date received | May 14, 2001 |
| Decision date | Jul 2, 2001 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | I-Stat Corp. |
| Location | Princeton, NJ, US |
| Contact | PAUL VANDERWERF |
| 510(k) history | 14 submissions · 14 cleared · 1989-2001 |

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