

K973897 DHEA-SNov 13, 1997
30 days to decisionK973897 · Product code: **JKC** · Chemistry
Source: <https://www.510kdatabase.net/k973897/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Dehydroepiandrosterone (free And Sulfate) (JKC) |
| Date received | Oct 14, 1997 |
| Decision date | Nov 13, 1997 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Kmi Diagnostics, Inc. |
| Location | Minneapolis, MN, US |
| Contact | MARK A KOWAL |
| 510(k) history | 6 submissions · 6 cleared · 1997-2002 |

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