

K951630 AURAFLEX PROGESTERONE 150TEST PACKMay 8, 1995
31 days to decisionK951630 · Product code: **JLS** · Chemistry
Source: <https://www.510kdatabase.net/k951630/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Progesterone (JLS) |
| Date received | Apr 7, 1995 |
| Decision date | May 8, 1995 |
| Days to decision | 31 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Organon Teknika Corp. |
| Location | Mchenry, IL, US |
| Contact | C. D KAFADER, II |
| 510(k) history | 130 submissions · 129 cleared · 1980-2000 |

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