

**K944697 AURA FLEX FT4 200 TEST PACK, FT4 CALIBRATOR
PACK**Feb 22, 1995
152 days to decisionK944697 · Product code: **CEC** · Chemistry
Source: <https://www.510kdatabase.net/k944697/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Sep 23, 1994
Decision date	Feb 22, 1995
Days to decision	152 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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