

K945331 AURAFLEX HCGMar 20, 1995
139 days to decisionK945331 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k945331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Nov 1, 1994
Decision date	Mar 20, 1995
Days to decision	139 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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