

K951685 AURAFLEX TESTOSTERONE CALIBRATOR PACKNov 14, 1995
218 days to decisionK951685 · Product code: **CDZ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Apr 10, 1995
Decision date	Nov 14, 1995
Days to decision	218 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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