

K780308 OREIA-T4Apr 12, 1978
48 days to decisionK780308 · Product code: **CDX** · Chemistry
Source: <https://www.510kdatabase.net/k780308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Thyroxine (CDX)
Date received	Feb 23, 1978
Decision date	Apr 12, 1978
Days to decision	48 days
Third-party review	No

APPLICANT

Company	Organon, Inc.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1977-1995

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k780308/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026