

K780401 THYRO-ZYME-T4 ASSAY KITApr 24, 1978
42 days to decisionK780401 · Product code: **CDX** · Chemistry
Source: <https://www.510kdatabase.net/k780401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Thyroxine (CDX)
Date received	Mar 13, 1978
Decision date	Apr 24, 1978
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Coulter Electronics, Inc.
Location	Mchenry, IL, US
510(k) history	101 submissions · 101 cleared · 1976-1994

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Device record: <https://www.510kdatabase.net/k780401/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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