

K952284 AMERLITE TBG ASSAYJul 26, 1995
71 days to decisionK952284 · Product code: **CEE** · Chemistry
Source: <https://www.510kdatabase.net/k952284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroxine-binding Globulin (CEE)
Date received	May 16, 1995
Decision date	Jul 26, 1995
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Johnson & Johnson Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	YVONNE E MIDDLEFELL
510(k) history	33 submissions · 33 cleared · 1995-1998

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