

**K970281 VITROS IMMUNODIAGNOSTIC PRODUCTS
PROLACTIN REAGENT PACK/CALIBRATORS**Feb 25, 1997
32 days to decisionK970281 · Product code: CFT · Chemistry
Source: <https://www.510kdatabase.net/k970281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Prolactin (lactogen) (CFT)
Date received	Jan 24, 1997
Decision date	Feb 25, 1997
Days to decision	32 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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