

**K970016 VITROS IMMUNODIAGNOSITCS PRODUCTS-FREE T3  
REAGENT PACK (GEM.1020)/FREE T3 CALIBRATORS  
(GEM.C020)**Jan 30, 1997  
28 days to decisionK970016 · Product code: **CDP** · Chemistry  
Source: <https://www.510kdatabase.net/k970016/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	Jan 2, 1997
Decision date	Jan 30, 1997
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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