

**K972133 VITROS IMMUNODIAGNOSTICS PRODUCTS
PROGESTERONE REAGENT PACK (GEM.1070),
PROGESTERONE CALIBRATORS (GEM.C070)**Jun 24, 1997
18 days to decisionK972133 · Product code: **JLS** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Progesterone (JLS)
Date received	Jun 6, 1997
Decision date	Jun 24, 1997
Days to decision	18 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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