

**K953826 ENZYME LINKED UMMINOABSORBENT ASSAY,  
RUBELLA**

Dec 14, 1995  
121 days to decision

K953826 · Product code: **GOM** · Microbiology  
Source: <https://www.510kdatabase.net/k953826/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Cf, Rubella (GOM)
Date received	Aug 15, 1995
Decision date	Dec 14, 1995
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pyramid Biological Corp.</b>
Location	Van Nuys, CA, US
Contact	JEANETTE R PORRETTA
510(k) history	12 submissions · 12 cleared · 1993-1997

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Device record: <https://www.510kdatabase.net/k953826/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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